SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

PRODUCT CATEGORY: ADVANCED WOUND CARE VelNez Nasal/ Ear Pack

Prepared By	Reviewed By	Approved By
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1.	**Device Identification and general information**	
1.1.	Device trade name (s)	VelNez
1.2.	Manufacturer's name and address	Plot no. 52-54,63 & 64, Roz Ka Meo Industrial Area Nuh, Distt. Mewat (Haryana) Pin- 122103, India
1.3.	Manufacturer's single registration number (SRN)	IN-MF-000010063
1.4.	Basic UDI-DI	8904340414A2
1.5.	Medical device nomenclature description / text	Based on the regulation (EU) 2017/745 of the European Parliament and of the council of 05April2017, Annex VIII (Classification rules). As per rule 18, device manufactured utilizing animal tissues or derivatives rendered non-viable, VelNez shall be classified as Class III medical device.
1.6.	Class of device	Class III
1.7.	Year when the first certificate (CE) was issued covering the device	2021
1.8.	Authorised representative if applicable; name and the SRN	MDI Europa GmbH, Langenhagener Str.71, 30855 Langenhagen Germany SRN: DE-AR-000006218
1.9	Notified Body's name (The NB that will validate the SSCP)	DNV Product Assurance AS, Norway CE 2460
2.	**Intended use of the device**	
2.1.	Intended purpose	VelNez is intended to be used as a packing dressing in the nasal cavity in Epistaxis, Rhinoplasty, Septoplasty, Rhinoseptoplasty, Functional Endoscopic Sinus Surgery (FESS), Sinoplasty, Turbinate reduction, surgery or trauma patients. It is also intended to be used in middle ear and external ear cavity after ear surgery, traumatic bleeding, tympanoplasty, tympanostomy or myringoplasty and other outer and middle ear surgeries. It acts as a space occupying dressing, preventing adhesion by separating the compromised mucosal surfaces. It also helps in healing and achieving haemostasis.
2.2.	Indication(s) and target population(s)	**Indication(s):** As a nasal packing dressing for haemorrhage control or/and prevention of adhesion in the nasal cavity in Epistaxis, Rhinoplasty, Septoplasty, Rhinoseptoplasty, Functional Endoscopic Sinus Surgery (FESS),

		Sinoplasty, Turbinate reduction, surgery or trauma patients. As an ear pack for haemorrhage control or/and prevention of adhesion between the mucosal surfaces in middle ear and external ear cavity after ear surgery, traumatic bleeding, tympanoplasty, tympanostomy or myringoplasty and other outer and middle ear surgeries. **Target Population(s):** Nasal/ Ear cavity surgery or trauma patients (18-60 years)
2.3.	Contraindications and / or limitations	i) No known contraindications and adverse reactions reported ii) Do not use VelNez if you are allergic (Hypersensitive) to its constituents.
3.	**Device Description**	
3.1.	Description of the device	VelNez, an optimal Healing Solution, is a biocompatible and fragmentable composite that fragments within a few days on the application intended as nasal or ear dressing. The pain associated with the traditional nasal dressing removal is eliminated with VelNez since such procedures are not necessary for the application of VelNez. As an ear dressing, VelNez degrades itself after implantation.
3.2.	A reference to previous generation(s) or variants if such exist, and a description of the differences	Not applicable. No previous generation of the device is produced
3.3.	Description of any accessories which are intended to be used in combination with the device	Not applicable. The device does not require any accessories to achieve its intended function
3.4.	Description of any other devices and products which are intended to be used in combination with the device	Not applicable
4.	**Risks and warnings**	
4.1.	Residual risks and undesirable effects	Refer to Annexure A
4.2.	Warnings and Precautions	i) Do not re-sterilize ii) Do not reuse iii) Use the device prior to the "Use by ( )" specified on package iv) To be used by Registered Medical Practitioner or a hospital only. v) Do not use if package is damaged. vi) Discontinue the use if the application area shows signs of infection, irritation, maceration (whitening of surrounding

		skin) or itching & consult a healthcare professional. vii) Should not be used for the patients with coagulation disorders
4.3.	Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable	Not Applicable
5.	**Summary of clinical evaluation and post-market clinical follow-up (PMCF)**	
5.1.	Summary of clinical data related to equivalent device, if applicable	Refer to Annexure B
5.2.	Summary of clinical data from conducted investigations of the device before and after the CE-marking, if applicable	Refer to Annexure C
5.3.	Summary of clinical data from other sources, if applicable	Refer to Annexure D
5.4.	An Overall summary of the clinical performance and safety	Results from the post marketing surveillance studies and ongoing routine market surveillance are very encouraging and it can be concluded that VelNez nasal/ear pack meets the performance requirements and is considered safe and effective nasal/ear pack after nasal/ear surgery.
5.5.	Ongoing or planned post-market clinical follow-up	Estimated date for the post-market clinical follow-up report – Apr/2024
6.	Possible diagnostic or therapeutic alternatives	VelNez is equivalent to Nasopore, Gelspon P & Gelfoam as all are used in nasal cavity and help in healing and achieving haemostasis in surgery or trauma patients. The device is physically, chemically and biologically equivalent to the commercially available products. Further, VelNez also includes Chitosan (Oyester mushroom). For chitosan, VelNez is comparable with Axiostat a chitosan-based haemostat. Some other similar devices in the market are Rapid Rhino, Nasastent, PosiSep X, Meropack, Surgispon, Merogel and Otopore.

7.	Suggested profile and training for users	For use by Health care professionals only. Users are required to refer to the IFU prior to use. User training provided by Datt MediProducts Private Limited
8.	Reference to any standards applied	Refer to Annexure E

9. Revision History

Date	**Amendments**				**Discard**		
	Version	**Pages**	**Specific No.**	**Reason**	**Version**	**Pages**	**Specific No.**
15-Mar-2023	1.0						
25-July-2023	2.0			Ear indication added, Ear & nasal clinical studies and relevant data included	1.0		

Annexure A: Residual risks and undesirable effects

Hazard	Harm	Benefits of VelNez	Residual Risk	Residual risk mitigation plan	Risk Vs. benefit analysis/outcome	Final Status
Complicated instruction for user	Misuse of device, reduced efficacy of the device	Effective haemostasis is vital to reduce the pain and mortality of patients. Both Gelatin & Chitosan are very well known for its haemostatic properties.	3R	Users are trained on IFU & understanding of symbols. Only trained medical practitioner can use this product"	As per PMS & clinical data no clinical incident/complaint is reported hence risk of difficulty in understanding of instruction for use is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis
Storage of the product not followed by the stockiest or end user	Adverse impact on patient health such as allergy, local reaction, inflammation	Effective haemostasis is vital to reduce the pain and mortality of patients. Both Gelatin & Chitosan are very well known for its haemostatic properties. Many studies results showed that the best blood-clotting index (BCI) was achieved with both.	3R	Storage conditions are printed on inner and outer pack. User Training is provided for safe use, storage of devices / usage within shelf life	As per PMS & clinical data no incident/complaint is reported hence risk of quality damage due to improper storage condition is outweighed by the benefits of the device	Acceptable after Risk - Benefit Analysis
Product used by the medical practitioner for unintended use	Adverse impact on patient health such as allergy, local reaction, inflammation	The better haemostatic effect is due to their ability to absorb blood platelets easily and to the higher liquid adsorption ratio. Chitosan, with good biocompatibility and non-toxicity, has been widely applied in biomedicine, industry. Gelatin conforms easily to wounds making it suitable for use in irregular wounds. It liquefies within two to five	3R	Product is used by Medical Practioner only Necessary instructions given in IFU under Contraindications, Warning, Precautions and adverse reactions and necessary symbols given on inner and outer label User Training is provided for safe use, storage of devices / usage within shelf life.	As per PMS & clinical data no incident/complaint is reported hence risk of product use by untrained practioner is very low/negligible hence it is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis

Product used after expiry date	Adverse impact on patient health such as allergy, local reaction, inflammation	days after application and is absorbed completely in four to six weeks.	4R	Date of Expiry is mentioned on Label Labels/ IFU are suitably controlled User Training is provided for safe use, storage of devices / usage within shelf life.	As per PMS & clinical data no incident/complaint is reported hence risk of quality damage due to improper storage condition is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis
Instructions for use not followed	Adverse impact on patient health such as allergy, local reaction, inflammation		4R	Symbol for – "read instruction for use" printed on inner and outer pack. User Training is provided for correct understanding of IFU & its correct use	As per PMS & clinical data no incident/complaint is reported hence risk of IFU not followed by doctor is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis
Re-sterilization of the product	Adverse impact on patient health such as allergy, local reaction, inflammation	Effective haemostasis is vital to reduce the pain and mortality of patients. Both Gelatin & Chitosan are very well known for its haemostatic properties. Many studies results showed that the best blood-clotting index (BCI) was achieved with both.	4R	Warning symbol for do not resterilise printed on inner pack, outer pack and IFU. User Training is provided for safe use, and cautioned on resterilization.	As per PMS & clinical data no incident/complaint is reported hence risk of resterilization is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis

Product used in uncontrolled condition	Adverse impact on patient health such as allergy, local reaction, inflammation	The better haemostatic effect is due to their ability to absorb blood platelets easily and to the higher liquid adsorption ratio. Chitosan (CS), with good biocompatibility and non-toxicity, has been widely applied in biomedicine, industry. Gelatin conforms easily to wounds making it suitable for use in irregular wounds. It liquefies within two to five days after application and is absorbed completely in four to six weeks.	4R	User Training is provided for safe use. Users are trained on IFU & understanding of symbols	VelNez is used by user in hospital environment which is conducive for safe use of device. As per PMS & clinical data no incident/complaint is reported hence risk of use in unsafe environment is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis
Reuse of product	Adverse impact on patient health such as allergy, local reaction, inflammation		4R	Warning symbol for do not reuse printed on inner pack, outer pack and IFU. User Training is provided for safe use, and cautioned on reuse	As per PMS & clinical data no incident/complaint is reported hence the risk of reuse is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis
Improper Disposal of expired/used device	Adverse impact on patient health such as allergy, local reaction, inflammation		4R	Instruction for use clearly defines the method of disposal as per national regulations for control of Biohazard waste User is also informed/trained not to use product after expiry date and same to be discarded as per national regulations	This product is not meant to be removed however in case it is removed user is cautioned for safe disposal of device as per national regulations. As per PMS & clinical data no incident/complaint is reported hence the risk of improper disposal is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis

If used on products who are allergic to Gelatin/Chitosan & other ingredients of product	Allergic response towards the local tissue reaction, inflammation, sensitization		4R	Warnings & Contraindications given in IFU To be used by medical practioner only User Training as per Usability validation plan Post market study covering search & analysis of any adverse event reported. Strict adherence to vigilance procedure	User Training is provided for safe use, and cautioned not to use on patients who are allergic to any active ingredients. As per PMS & clinical data no incident/complaint is reported hence this risk is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis
Product used on patient with coagulation disorder	Increase in the clotting time	Effective haemostasis is vital to reduce the pain and mortality of patients. Both Gelatin & Chitosan is very well known for its haemostatic properties. Many studies results showed that the best blood-clotting index (BCI) was achieved with both. The better haemostatic effect is due to their ability to absorb blood platelets	3R	Warnings & Contraindications given in IFU To be used by medical practioner only User Training as per Usability validation plan Post market study covering search & analysis of any adverse event reported. Strict adherence to vigilance procedure	User Training is provided for safe use, and cautioned not to use on patients who have coagulation disorder As per PMS & clinical data no incident/complaint is reported hence this risk is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis

Product use continued even after the signs of infection, irritation.	Allergic response towards the local tissue reaction, inflammation, sensitization	easily and to the higher liquid adsorption ratio. Chitosan (CS), with good biocompatibility and non-toxicity, has been widely applied in biomedicine, industry. Gelatin conforms easily to wounds making it suitable for use in irregular wounds. It liquefies within two to five days after application and is absorbed completely in four to six weeks.	4R	Warnings & Contraindications given in IFU To be used by medical practioner only User Training as per Usability validation plan Post market study covering search & analysis of any adverse event reported. Strict adherence to vigilance procedure	User Training is provided for safe use, and cautioned not to use on patients if they develop any signs of irritation/infection As per PMS & clinical data no incident/complaint is reported hence this risk is outweighed by the benefits of the device	Acceptable after Risk Benefit Analysis

Annexure B: Summary of clinical data related to equivalent device

Product name of equivalent / Similar device	Intended purpose	Intendedusers	Intended patient population	Medical condition	Indication	Reference to clinical data evaluation in the CER (Date, version and location in the text)
GELFOAM	GELFOAM is a Sterile sponge, used dry or saturated with sterile sodium chloride solution, indicated as a hemostatic device.	Clinical Practitioner	Patients undergoing nasal surgeries and oral and dental surgery.	Functional endoscopic sinus surgery and tooth extraction	Hemostasis	Clinical Evaluation Report: DMP-CER-R-017N, Version 3.0 dated 25.07.2023 Section 4.2 Demonstration of equivalence
GelSpon	GelSpon is an absorbable surgical haemostatic sponge	Clinical Practitioner	Plastic surgery, General surgery, ENT and Dental surgery, Orthopedic surgery, Abdominal surgery, Neuro surgery, Dermatology, Gynecology, Ano-rectal surgery.	ENT Surgeries	Hemostasis	Clinical Evaluation Report: DMP-CER-R-017N, Version 3.0 dated 25.07.2023 Section 4.2 Demonstration of equivalence
Axiostat	Indicated to control bleeding of lacerations, minor cuts and abrasions, Nasal Bleeding, Dental Abrasion etc.	Clinical Practitioner	The dressing is indicated for the following wounds: lacerations, abrasions, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.	The dressing is indicated for the following wounds: lacerations, abrasions, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.	Axiostat Patch is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing for patients and for the	Clinical Evaluation Report: DMP-CER-R-017N, Version 3.0 dated 25.07.2023 Section 4.2 Demonstration of equivalence

Product name of equivalent / Similar device	Intended purpose	Intendedusers	Intended patient population	Medical condition	Indication	Reference to clinical data evaluation in the CER (Date, version and location in the text)
					rapid control of moderate to severe bleeding.	
Rapid Rhino Nasastent	NASASTENT nasal dressing is intended to minimize bleeding and edema and to prevent adhesions between the septum and the middle turbinate after surgery or trauma.	Clinical Practitioner	Patients undergoing nasal surgeries	ENT surgeries	Post operative Dressing	Clinical Evaluation Report: DMP-CER-R-017N, Version 3.0 dated 25.07.2023 Section 4.2 Demonstration of equivalence
PosiSep X	Hemostat Dressing/Intranasal Splint is indicated for use in patients undergoing nasal/sinus surgery as a space occupying splint and hemostat to treat epistaxis	Clinical Practitioner	Patients undergoing nasal surgeries	ENT surgeries	Post operative Dressing	Clinical Evaluation Report: DMP-CER-R-017N, Version 3.0 dated 25.07.2023 Section 4.2 Demonstration of equivalence
Nasopore	Nasopore is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following surgery or nasal trauma by tamponade effect and blood absorption.	Clinical Practitioner	Patients undergoing nasal surgeries	ENT surgeries	Post operative Dressing	Clinical Evaluation Report: DMP-CER-R-017N, Version 3.0 dated 25.07.2023 Section 4.2 Demonstration of equivalence

Product name of equivalent / Similar device	Intended purpose	Intendedusers	Intended patient population	Medical condition	Indication	Reference to clinical data evaluation in the CER (Date, version and location in the text)
Meropack	MeroPack® Bioresorbable Nasal Dressing and Sinus Stent is intended for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces during mesothelial cell regeneration in the nasal cavity; help control minimal bleeding following surgery or nasal trauma by tamponade effect, blood absorption and platelet aggregation; and to help prevent lateralization of the middle turbinate during the postoperative period.	Clinical Practitioner	Patients undergoing nasal surgeries	ENT surgeries	Post operative Dressing	Clinical Evaluation Report: DMP-CER-R-017N, Version 3.0 dated 25.07.2023 Section 4.2 Demonstration of equivalence
Surgispon	SURGISPON is a surgical haemostatic sponge, manufactured from highly purified first extract grade gelatine material for use in various surgical procedures, where traditional haemostatic methods are difficult or impractical and use of other non-absorbable materials is undesirable	Not Defined	The patient undergoing abdominal, anorectal, dental, ENT, genito urinary surgery, gynaecological, neuro, orthopaedic, otolaryngological, vascular, spinal, tumour, hepatic surgery and hysterectomy	The dressing is indicated for abdominal, anorectal, dental, ENT, genito urinary surgery, gynaecological, neuro, orthopaedic, otolaryngological, vascular, spinal, tumour, hepatic surgery and hysterectomy	Hemostasis	Clinical Evaluation Report: DMP-CER-R-017N, Version 3.0 dated 25.07.2023 Section 4.2 Demonstration of equivalence

Product name of equivalent / Similar device	Intended purpose	Intended users	Intended patient population	Medical condition	Indication	Reference to clinical data evaluation in the CER (Date, version and location in the text)
OtoPore	Otopore is a fragmentable ear packing and is indicated for use in patients undergoing ear surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following ear surgery by tamponade effect and blood absorption.	Only trained and experienced healthcare professionals should use this product.	Patients undergoing ear surgeries	The dressing is indicated for use in patients undergoing ear surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following ear surgery by tamponade effect and blood absorption.	Hemostasis	Clinical Evaluation Report: DMP-CER-R-017N, Version 3.0 dated 25.07.2023 Section 4.2 Demonstration of equivalence
Merogel Ear Packing	MeroGel® Otologic Packing is a space-occupying dressing and/or stent intended to separate mucosal surfaces, help control minimal bleeding, and act as an adjunct to aid in the natural healing process.	Not Defined	Patients undergoing ear surgeries	The dressing is indicated for use in patients undergoing ear surgery as a space-occupying dressing and/or stent intended to separate mucosal surfaces, help control minimal bleeding, and act as an adjunct to aid in the natural healing process.	Hemostasis	Clinical Evaluation Report: DMP-CER-R-017N, Version 3.0 dated 25.07.2023 Section 4.2 Demonstration of equivalence

Annexure C: Summary of clinical data from conducted investigations of the device before and after the CE-marking

S No.	Details	VelNez® Nasal Pack
1.	Study title	A post marketing surveillance study (PMS) to evaluate safety and tolerability of VelNez® as a nasal pack after nasal Surgery.
2.	Protocol No.	DMPL/P05-2017/CT/VN
3.	Version No.	Version: 2.0
4.	CTRI No.	CTRI/2018/12/016535
5.	Date of first subject enrolled	18 December 2018
6.	Date of last subject completed	15 October 2019
7.	Investigators and study centres	Dr Parusharam Nagula (Principal Investigator) Head of Department of E.N. T. Mahatma Gandhi Memorial Hospital, Warangal Kakatiya Research Centre, Mahatma Gandhi Memorial Hospital, Mahatma Gandhi Road Warangal, Telangana, 506007, India
8.	Total number of subjects	40 Subjects
9	Date of Final Report	31 July 2020

S No.	Details	VelNez® Nasal Pack
1.	Study title	A post marketing surveillance study (PMS) to evaluate safety and tolerability of VelNez® as a nasal pack after nasal Surgery.
2.	Protocol No.	DMPL/P05-2017/CT/VN
3.	Version No.	Version: 2.0
4.	CTRI No.	CTRI/2018/12/016535
5.	Date of first subject enrolled	28 January 2019
6.	Date of last subject completed	17 February 2020
7.	Investigators and study centres	Dr Shama Bellad (Principal Investigator) K.L.E.S. Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, KARNATAKA Belgaum KARNATAKA, India
8.	Total number of subjects	36 Subjects
9	Date of Final Report	09 December 2020

In these studies of VelNez, Haemorrhage control within 20 minutes of surgery was evaluated. 36.84 % of subjects had haemorrhage control within 5 minutes of surgery, and 27.63% of subjects had haemorrhage control within the range of 5-10 mins. 35.52% of subjects had shown

haemorrhage control within the range of 10-15 mins. There was no subject data reported as haemorrhage failure and the average haemorrhage control time was 7.49±3.9 mins.
Relief from post operative pain was evaluated through Pain VAS Scale from surgery day to follow up 9. 67.10% of subjects reported pain on surgery day which was reduced to 34.24% at follow up 4 and further only 1.35% population had shown pain at follow up 8. There was no pain reported by any patients from follow up 9.
Relief from moderate pain and nasal obstruction were also evaluated through Pain VAS Scale from surgery day to follow up 9 (Day 28). Moderate pain and obstruction were defined as 5 on the scale (VAS) of 1-10. 15.78% subjects reported moderate pain on surgery day. None of the subjects reported moderate pain from follow up 3 onwards. 42% subject population reported moderate obstruction on the baseline, and 10% on surgery day. None of the subjects reported obstruction from follow up 3 onwards. Infection at the site of VelNez application was reported in 2.6% of subject proportion at baseline, none of the subject's reported infection at the site on subsequent visit.

Results from this studied are very encouraging and it can be concluded that VelNez nasal pack is safe and effective nasal pack after nasal surgery.

Further, VelNez was assessed for safety and tolerability as an ear pack in an independent clinical study. A brief summary and results of the study are as follows:

S. No.	Details	VelNez Ear Pack
1.	Study title	A post marketing surveillance (PMS), single centric study to evaluate safety and tolerability of VelNez as a space occupying dressing pack after ear surgery.
2.	Investigational Product	VelNez ear pack
3.	Protocol No. Protocol Version Protocol Date Revision Number Revision Date	DMPL/CIP-006-2022/CT/VN 1.0 1.0 04-Oct-2022 None None
4.	Development Phase	PMS Study
5.	Study Sponsor	**Datt Mediproducts Private Limited** 56, Community Centre, East of Kailash, New Delhi -110065, India
6.	Investigators and study centres	**Dr. Akhil Pratap Singh** (Principal Investigator) Associate Professor, Department of ENT Sarojini Naidu Medical College, Moti Katra. Agra - 282002 (U.P)
7.	Date of first subject enrolled	10-Mar-2023
8.	Date of last subject completed	03-Apr-2023
9.	Version & Date of Final Report	1.0, 12 Jul 2023

In this study, Haemorrhage control within 20 minutes of VelNez application after surgery was evaluated.

85.7% (18) subjects reached favourable endpoint by visit 6, while 38.1% (8) subjects received favourable endpoint by visit 5 and 1(4.8%) subject reached favourable endpoint by visit 4. Moderate pain is defined as 5 on scale (VAS) of 1 (No Pain)-10 (Worst Pain). None of the subjects reported moderate pain at any of the study visits. None of the subjects reported moderate pain from surgery day to follow up visit 10. All 21(100%) subjects showed no infection at visit 11(Day of discharge has been counted as a visit in statistical analysis). 20(95.2%) subjects showed no pressure effect in the ear canal, due to the application of the VelNez ear pack at visit 11(Day of discharge has been counted as a visit in statistical analysis. Surgeons' questionnaire was used to evaluate the use of the device. 1-5 rating on Likert scale was market where 1 denoted the easy and 5 denoted difficult. Surgeon has rated device response of 1 for the appropriateness of instruction for use, Conformance to tissue surfaces, Ease of application & Ease of handling. There was 1 adverse event (AE) reported in the study which were not related to the study product and got resolved. There were no SAE's recorded in the study.

Results from this study are very encouraging and it can be concluded that VelNez ear pack meets the performance requirements and is considered safe and effective ear pack after ear surgery.

After CE-marking:

A post marketing surveillance clinical study was conducted after CE marking and a brief summary and findings of the conducted study are presented as follows:

S No.	Details	VelNez Nasal Pack
1.	Study title	A post marketing surveillance study (PMS) to evaluate safety and tolerability of VelNez as a nasal pack after nasal Surgery.
2.	Protocol No.	DMPL/CIP-002-2021/CT/VN
3.	Version No.	Version: 1.0, 24 June 2021
4.	CTRI No.	CTRI/2021/09/036437
5.	Date of first subject enrolled	27 October 2021
6.	Date of last subject completed	24 February 2022
7.	Investigators and study centres	**Dr. Akhil Pratap Singh** (Principal Investigator) Assistant professor Department of ENT Sarojini Naidu Medical College, Moti Katra. Agra - 282003 (U.P)
8.	Total number of subjects	20 subjects
9	Version & Date of Final Report	1.0, 28 Oct 2022

A post marketing surveillance study (DMPL/CIP-002-2021/CT/VN) to evaluate safety and tolerability of VelNez® as nasal pack after nasal surgery was performed at Sarojini Naidu Medical College, Moti Katra. Agra. After informed consent and evaluation of inclusion criteria, 20 subjects were included, with ages ranging from 18 to 54 years.

Following are the main findings of the PMS study of VelNez:

- All 20 (100%) subjects had haemorrhage control within 20 mins of application of VelNez nasal pack.
- Relief from moderate pain was evaluated through Pain VAS Scale from surgery day to follow up Visit 10. None of the subject reported moderate pain at any of the study visits.
- Nasal obstruction was evaluated through Scale (0-10) from surgery day to follow up visit 9. Moderate obstruction is defined as 5 on scale of 0-10. 4 subjects (20%) reported moderate obstruction on Visit 1, 5(25%) on visit 2, 1(5%) subject on visit 3. None of the subjects reported obstruction visit 3 onwards.
- Infection at site of VelNez application was reported for none of the subjects as baseline, none of subjects reported infection at site for subsequent visit.
- All 20(100%) Subjects demonstrated no adhesion at visit 10.
- At visit 8, 9 and visit 10 none of the subjects reported pressure due to VelNez® application
- Nasal discharge was evaluated on Likert scale of 0-10. 2 Subjects reported moderate discharge (n=2, 10%) at visit 1, 19 subjects (95%) reported no discharge at visit 9 and visit 10

Results from current study are very encouraging and it can be concluded that VelNez nasal pack is safe and effective a nasal pack in subjects undergoing for planned nasal surgery.

VelNez, fulfils all the criteria for an effective dressing. In conclusion, we can say that VelNez manufactured by Datt Mediproducts Pvt. Ltd. is safe and secure to use in patients with nasal/ cavity in surgery or traumatic bleeding.

Annexure D: Summary of clinical data from other sources:

Total 80 literatures were selected from period 2010 – 2023 for detailed review and safe use & performance/benefits of gelatin and chitosan-based sponge nasal/ear dressing. Refer Annexure-I for detailed literatures and cited articles.

a) Selection criteria used to select articles

Pubmed, Cochrane Library database and clinicaltrials.gov were used for literature search and any trial regarding equivalent device Gelfoam, Gelspon and Axiostat. The search was limited to articles published mainly over the last ten years in English language. In addition, older publications were used to provide a background for the subject. Searches were screened and those studies thought to be relevant had full text versions retrieved. The references of all retrieved texts were searched for further relevant studies. Selection criteria for the literature search are based on the equivalent/ similar nature of product, indication (intended use), physical properties etc., complication, safety and its limitations. Duplicate publications (superseded by another publication by same authors and same purpose) and devices not intended for hemostat, nasal/ear application, different active ingredients than gelatin or chitosan were excluded.

(b) Table given below further presents the number of potential articles resulting from the search terms. The search criteria were limited to the devices in Table given below. In addition, the search was limited to Human studies and articles that were in English only. The search was conducted for all studies where device was used during treatment.

Media	**Search Word**	**Limitations**	**Results Hits**	**Usable Hits**	**Excluded Hits**	**Reason of exclusion**
Cochrane Library	Gelatin nasal sponge	Main focus was on studies including both Gelatin (porcine origin) and Chitosan (Source mushroom) and equivalent devices	15	3	12	Reason for excluded hits as our main focus was on equivalent device, nasal application and full literature
	Chitosan nasal dressing		5	2	3	
	"Nasal Dressing"		42	10	32	
	"Nasal Pack"		29	03	26	
	Septoplasty dressing		16	03	13	
	"Sinus surgery dressing"		00	00	00	
	Axiostat		06	00	06	
	Meropack		01	00	01	
	Gelspon p		00	00	00	

	Gelfoam and "Nasal Pack"		05	00	05	
	Nasopore		39	06	33	
	Posisep X		00	00	00	
	Rapid Rhino Nasastent		00	00	00	
	"MeroGel"		5	1	4	
	otopore		0	0	0	
	"ear dressing"		1	0	1	
	SURGISPON®		1	0	1	
	Tympanoplasty Dressing		7	2	5	
	ear-pack AND surgery		9	3	6	
	chitosan AND ear		2	0	2	
	"myringoplasty dressing"		0	0	0	
	middle ear pack		35	14	21	
PubMed	Gelatin nasal sponge	Main focus was on studies including both Gelatin (porcine origin) and Chitosan(Source mushroom) and equivalent devices	72	06	66	Reason for excluded hits is that these were repeated as same were found & included as found relevant in other sites and main focus was on equivalent device
	Chitosan nasal dressing		12	05	07	
	"Nasal Dressing"		25	06	19	
	"Nasal Pack"		59	07	52	
	Septoplasty dressing		26	02	24	
	"Sinus surgery dressing"		205	16	189	
	Axiostat		04	00	04	
	Meropack		00	00	00	
	Gelspon p		00	00	00	
	Gelfoam and "Nasal Pack"		04	02	02	
	Nasopore		45	14	31	
	Posisep X		00	00	00	

	Rapid Rhino Nasastent		00	00	00	
	"MeroGel"		7	1	6	
	otopore		1	0	1	
	"ear dressing"		2	0	2	
	SURGISPON®		2	0	2	
	Tympanoplasty Dressing		15	2	13	
	ear-pack AND surgery		3	1	2	
	chitosan AND ear		109	0	109	
	"myringoplasty dressing"		4	0	4	
	middle ear pack		36	5	31	
Clinicaltrials.gov	Gelatin nasal sponge	Main focus was on new studies. But could not access latest data as most of the trials were not completed (in progress)	00	5	31	Reason for excluded hits as our main focus was on equivalent device, nasal application and full literature
	Chitosan nasal dressing		01	01	00	
	"Nasal Dressing"		11	01	10	
	"Nasal Pack"		28	01	27	
	Septoplasty dressing		00	00	00	
	"Sinus surgery dressing"		08	00	08	
	Axiostat		03	00	03	
	Meropack		01	00	01	
	Gelspon p		00	00	00	
	Gelfoam and "Nasal Pack"		00	00	00	
	Nasopore		04	00	04	
	Posisep X		00	00	00	
	Rapid Rhino Nasastent		00	00	00	

	"MeroGel"		0	0	0	
	otopore		0	0	0	
	"ear dressing"		26	0	26	
	SURGISPON®		1	0	1	
	Tympanoplasty Dressing		3	0	3	
	ear-pack AND surgery		0	0	0	
	chitosan AND ear		1	0	1	
	"myringoplasty dressing"		0	0	0	
	middle ear pack		4	0	4	

***Total 121 usable hits were found for literature. Out of which 41 literatures were repeated with different keywords.**

(c) Selection criteria for bibliography

The selection for inclusion in bibliography was based on meeting any one or more of the following criteria:

- Relevance of Product Design
- Patient age group
- Intended use
- Material used
- Efficacy Measures: outcome measures such as comfort, no pain, etc (general, procedure related)

(d) Inclusion Criteria

Studies with equivalent devices for effectiveness of the VelNez.

(e) Study Design including:

- Randomized, non-randomized, controlled, observational trials
- Observational studies with statistically powerful population.

(f) Patient Population: Safe for Human Use (Adult Males and Females)

(g) Language: English Articles

(h) Exclusion criteria

- Duplicate publications (superseded by another publication by same authors and same purpose)
- Isolated case reports.
- Studies with population / number of patients less than 10 unless they reported complications.
- Publication language other than English
- Literature on device with different intended use

(i) Journal selection

Screening and selection of the literature to identify relevance to the effectiveness of the VelNez were carried out in reference to the methodology shown below, as per MEDEV 2.7.1: Rev 04 2016.

Choose data classification

The data was selected and saved based on its relevance to Performance, safety, design feature of medical device

The List of clinical tables used in evaluation

S. No.	Paper Title	Year	Perform-ance & Safety	Intended application (Absorbable Nasal application for less pain, fast hemostasis, healing, less adhesion or no adhesion)
1	Effectiveness of hemostatic gelatin sponge as a packing material after septoplasty: A prospective, randomized, multicenter study Sung-Dong Kim, Sung-Lyong Hong, Min-Jung Kim, Joo-Yeon Kim, Yong-Wan Kim, Soo-Kweon Koo, Kyu-Sup Cho	2017	Yes	Yes
2	The Efficacy of Cutanplast Nasal Packing After Endoscopic Sinus Surgery: A Prospective, Randomized, Controlled Trial Kyu-Sup Cho, Seung-Kuk Shin, Jung-Hoon Lee, Joo-Yeon Kim, Soo-Kweon Koo, Yong-Wan Kim, Min-Jung Kim, Hwan-Jung Roh	2013	Yes	Yes
3	Comparative analysis of Cutanplast and Spongostan nasal packing after endoscopic sinus surgery: a prospective, randomized, multicenter study Kyu-Sup Cho, Chan-Hwi Park, Sung-Lyong Hong, Min-Jung Kim, Joo-Yeon Kim, Yong-Wan Kim, Soo-Kweon Koo, Hwan-Jung Roh	2015	Yes	Yes
4	Comparison between Gelfoam packing and no packing after endoscopic sinus surgery in the same patients Jee Hye Wee, Chul Hee Lee, Chae Seo Rhee, Jeong-Whun Kim	2012	Yes	Yes

5	Development and Physicochemical Analysis of Genipin-Crosslinked Gelatine Sponge as a Potential Resorbable Nasal Pack Jegadevswari Selvarajah, Mohd Fauzi Mh Busra, Aminuddin Bin Saim, Ruszymah Bt Hj Idrus & Yogeswaran Lokanathan	2020	Yes	Yes
6	A New Gelatine-based Hemostat for Sinonasal Surgery: A Clinical Survey TANJA HILDENBRAND	2013	Yes	Yes
7	Biodegradable Nasal Packings for Endoscopic Sinonasal Surgery: A Systematic Review and Meta-Analysis Maoxiao Yan1, Dandan Zheng1, Ying Li1, Qiaoli Zheng2, Jia Chen1, Beibei Yang1	2014	Yes	Yes
8	Comparative study between absorbable and Non-Absorbable nasal packings after nasal surgeries Ayman Abdelaal Mohamady, Hossam Abdelhay Gad, Ashraf Salah El-Hamshary, Dalia Ragab Abd-Elmaksoud, Abd-Elhakeem Fouad Ghallab	2020	Yes	Yes
9	Nasal packing in endonasal surgery - a literature review Claudiu Manea, Iulia Sabaru, Cristina Sanda Sfanta Maria Hospital, ENT&HNS Department, Bucharest, Romania	2011	Yes	Yes
10	Implementing Methods to Improve Perioperative Hemostasis in the Surgical and Trauma Settings DEBORAH J. NEVELEFF; LARRY W. KRAISS, MD doi: 10.1016/j.aorn.2010.08.006 © AORN, Inc, 2010	2010	Yes	Yes
11	A novel gelatin sponge for accelerated hemostasis Reiner Hajosch, Markus Suckfuell, Steffen Oesser, Michael Ahlers, Klaus Flechsenhar, Burkhard Schlosshauer	2010	Yes	Yes

12	https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/gelatin-sponge.Gelatin sponges have been used for culturing both preadipocytes and human mesenchymal stem cells (MSCs) for soft tissue engineering purposes.127,158,160 Additionally, microspheres made of gelatin have been widely used for adipose tissue engineering.	2017	Yes	Yes
13	Advances in Topical Hemostatic Agent Therapies: A Comprehensive Update Liang Huang . Geoffrey L. Liu . Alan D. Kaye . Henry Liu	2020	Yes	Yes
14	A clinical trial to study the effects of study product (Gelatin Sponge) in Controlling Bleeding during Intraoperative Procedures Name Dr Anil Mavila	2020	Yes	Yes
15	Evaluation of chitosan-based nasal dressing in animal model Zalán Piski , Imre Gerlinger , Eszter Tóth , István Háromi , Nelli Nepp , László Lujber	2018	Yes	Yes
16	Endoscopically guided chitosan nasal packing for intractable epistaxis Alan H. Shikani, Karim A. Chahine, and Mohannad A. Alqudah	2011	Yes	Yes
17	Influence of chitosan-based dressing on prevention of synechia and wound healing after endoscopic sinus surgery: A meta-analysis Jie Liu, Quan Zeng, Xia Ke, Yucheng Yang, Guohua Hu, and Xuan Zhang	2017	Yes	Yes
18	Efficacy of chitosan dressing on endoscopic sinus surgery:a systematic review and meta-analysis Jing-chun Zhou, Jing-jing Zhang, Wei Zhang, Zhao-yang Ke, Bo Zhang	2017	Yes	Yes
19	Efficacy and Safety of 3 Nasal Packing Materials Used After Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis: A Comparative Study in China Xi-Ling Zheng, Yu-Xiang Zhao, Min Xu	2017	Yes	Yes

20	A Randomised controlled study to evaluate the effect of Chitogel versus Hydrogel on wound healing and patient experience following endoscopic sinus surgery Dr Kevin Zheng	2021	Yes	Yes
21	Chitosan-Based Composite Materials for Prospective Hemostatic Applications Zhang Hu, ID , Dong-Ying Zhang, Si-Tong Lu, Pu-Wang Li and Si-Dong Li,	2018	Yes	Yes
22	Chitosan Modification and Pharmaceutical/Biomedical Applications Jiali Zhang, Wenshui Xia, Ping Liu, Qinyuan Cheng, Talba Tahirou, Wenxiu Gu and Bo Li	2010	Yes	Yes
23	Effect of a Chitosan Gel on Hemostasis and Prevention of Adhesion After Endoscopic Sinus Surgery Young-Jun Chung, Se-Young An, [...], and Ji-Hun Mo	2016	Yes	Yes
24	CHITOSAN-DERIVATIVES AS HEMOSTATIC AGENTS: THEIR ROLE IN TISSUE REGENERATION Mercy HP, Halim AS, Hussein AR	2012	Yes	Yes
25	Pharmaceutical Uses of Chitosan in the Medical Field ALEF MUSTAFA&EMIN CADAR &RODICA SÎRBU	2015	Yes	Yes
26	BIODEGRADABILITY OF CHITOSAN BASED PRODUCTS. Adina MATICA, Gheorghița MENGHIU, Vasile OSTAFE	2017	Yes	Yes
27	Pre-hospital Hemorrhagic Control Effectiveness of Axiostat® Dressing Versus Conventional Method in Acute Hemorrhage Due to Trauma Mohamed Kabeer 1 , P. P. Venugopalan 2 , V. C. Subhash 3	2019	Yes	Yes

28	Assessing the Efficacy of Haemostatic Dressing Axiostat® In Trauma Care at a Tertiary Care Hospital in India: A Comparison with Conventional Cotton Gauze Patel Ketan, Patel Aali, Patel Rignesh, Patel Bhavika, Parmar Priyank, Patel Dev	2016	Yes	Yes
29	The clinical outcomes of new hyaluronan nasal dressing: A prospective, randomized, controlled study Runjie Shi, Jiaqing Zhou, Bingshun Wang, Qingwei Wu, Yuling Shen, Peihua Wang, Jiadong Wang, Yunyun Wang, Ying Chen, and Xiao Zheng Shu	2013	Yes	Yes
30	Influence of hyaluronan nasal dressing on clinical outcome after endoscopic sinus surgery: A systematic review and meta-analysis Jianneng Chen, Xuan Wang, Luzan Chen, and Jie Liu	2017	Yes	Yes
31	The evaluation of two new hyaluronan hydrogels as nasal dressing in the rabbit maxillary sinus Qun Chen, Guangbin Sun, Yunyun Wang, Weiping Zhong, and Xiao Zheng Shu	2012	Yes	Yes
32	Evaluation of fully biodegradable nasal packings in functional endoscopic sinus surgery – a multi-centre study Dariusz Jurkiewicz , Henryk Kaźmierczak , Marek Rogowski , Paweł K Burduk , Barbara Gałusza , Wojciech Kaźmierczak , Bartosz Piszczatowski , Małgorzata Różańska , Rafał Sienicki , Kornel Szczygielski , Małgorzata Wierzchowska , Joanna Kuśmierczyk	2015	Yes	Yes
33	A Comparative Double Blind Study of Nasal Dressing Sponge®versus Merocel®as Nasal Pack after Nasal Surgery Lorusso Francesco, Dispenza Francesco, Sireci Federico, Modica-Domenico Michele, Gallina Salvatore	2021	Yes	Yes
34	The clinical outcomes of using a new cross-linked hyaluronan gel in endoscopic frontal sinus surgery Teoman Dal, Secil Bahar	2017	Yes	Yes

35	Comparison of Bioabsorbable Steroid-Eluting Sinus Stents Versus Nasopore After Endoscopic Sinus Surgery: A Multicenter, Randomized, Controlled, Single-Blinded Clinical Trial Zhenxiao Huang, Bing Zhou, Dehui Wang, Hongrui Zang, Huankang Zhang, Huan Wang, Shenqing Wang, Lei Cheng, Jinrang Li, Wenying Wu, Huifang Zhou and Huili Wu	2022	Yes	Yes
36	Bioabsorbable dressing impregnated with betamethasone and ciprofloxacin after endoscopic sinus surgery: A randomized, double-blind, placebo-controlled study Małgorzata Wierzchowska, Paulina Kalinczak-Górna, Błazej Grzeskowiak, Kamil Radajewski, Jakub Burduk, and Paweł Burduk	2021	Yes	Yes
37	Role of Nasal Packing in Surgical Outcome for Chronic Rhinosinusitis With Polyposis Ayşegül Verim, Lütfü Seneldir, Bariş Naiboğlu, Çiğdem Tepe Karaca, Semra Külekçi, Sema Zer Toros, Çağatay Oysu	2014	Yes	Yes
38	Nasal septal packing: which one? Engin Acıog˘lu, Deniz Tuna Edizer,O¨zgur Yigit, Fırat Onur, Zeynep Alkan	2012	Yes	Yes
39	Clinical benefits of polyurethane nasal packing in endoscopic sinus surgery Zalan Piski, Imre Gerlinger, Nelli Nepp, Peter Revesz, Andras Burian, Kornelia Farkas, Laszlo Lujber	2017	Yes	Yes
40	Comparison of post-operative morbidity between vaseline soaked ribbon gauze and nasopore following endoscopic septoturbinoplasty R Singh	2020	Yes	Yes
41	Polyurethane Versus Chitosan-Based Polymers Nasal Packs After Functional Endoscopic Sinus Surgery: A Prospective Randomized Double-Blinded Study Ahmed Gamal Khafagy, and Ahmed Mahmoud Maarouf	2021	Yes	Yes
42	Intranasal packs and haemostatic agents for the management of adult epistaxis: systematic review I Z Iqbal, G H Jones, N Dawe, C Mamais, M E Smith, R J Williams, I Kuhn, S Carrie	2017	Yes	Yes

43	Rapid Rhino versus Merocel nasal packs in septal surgery A HESHAM, A GHALI	2011	Yes	Yes
44	A comparative study on nasal packing after septoplasty: does it matter in terms of patient comfort, bleeding, and crust or synechia formation? Ayça E Özbal Koç , Seda Türkoğlu Babakurban, Sermin Sayan Kibar, Fuat Büyüklü	2016	Yes	Yes
45	Clinical outcome and patient satisfaction using biodegradable (NasoPore) and non-biodegradable packing, a double-blind, prospective, randomized study Pawel Krzysztof Burduk, Malgorzata Wierzchowska, Blazej Grześkowiak, Wojciech Kaźmierczak, Katarzyna Wawrzyniak	2017	Yes	Yes
46	The effects of Vaseline gauze strip, Merocel, and Nasopore on the formation of synechiae and excessive granulation tissue in the middle meatus and the incidence of major postoperative bleeding after endoscopic sinus surgery Ying-Piao Wang, Mao-Che Wang, Yu-Chun Chen, Yi-Shing Leu, Hung-Ching Lin, Kuo-Sheng Lee	2011	Yes	Yes
47	Patient comfort following FESS and Nasopore® packing, a double blind, prospective, randomized trial K.G. Kastl - M. Reichert - M.O. Scheithauer - F. Sommer - U. Kisser - T. Braun - M. Havel - A. Leunig	2014	Yes	Yes
48	The comfort of patients with different nasal packings after endoscopic sinus surgery for chronic rhinosinusitis A protocol for network meta-analysis Fuhong Zhang, Ji Chen, Xunwen Lei, Xiaowan Chen, Xiaobing Zhang	2019	Yes	Yes
49	Evaluation of the effect of Nasopore on nasal packing in functional endoscopic sinus surgery W Q Hu, Y M Shan, L N He, W M Xu, H Zhang	2016	Yes	Yes
50	Effects of four different nasal packing materials after endoscopic sinus surgery Y Q Duan, G G Chen, Y L Li, B Q Wang	2016	Yes	Yes

51	Comparative study between biodegradable nasopore (BNP) and Merocel hemox 10 cm after septo-turbinoplasty procedure A Romano, G Salzano, G Dell'Aversana Orabona, A Cama, M Petrocelli, P Piombino, F Schonauer, G Iaconetta, F A Salzano, L Califano	2017	Yes	Yes
52	Aspiration of Nasopore nasal packing Jonathan Smith, Ekambar Reddy	2017	Yes	Yes
53	Comparison study of the use of absorbable and nonabsorbable materials as internal splints after closed reduction for nasal bone fracture Chang Ryul Yi, Young Joon Kim, Hoon Kim, Sang Hyun Nam, Young Woong Choi	2014	Yes	Yes
54	Merocel versus Nasopore for nasal packing: a meta-analysis of randomized controlled trials Jianzhang Wang, Changping Cai, Shili Wang	2014	Yes	Yes
55	A Prospective Double-Blinded Randomized Controlled Study Comparing the Efficacy of a Novel Biodegradable Synthetic Polyurethane Foam (Nasopore) vs Standard Polyvinyl Acetate Sponge (Merocel) as Packing Material after Functional Endoscopic Sinus Surgery: The First Indian Experience S Raghunandhan, Mohan Kameswaran, John K Thomas	2014	Yes	Yes
56	Wound healing in endoscopic sinus surgery: Phase 1 clinical trial evaluating the role of Chitogel with adjuvants Rajan Sundaresan Vediappan, Catherine Bennett, Clare Cooksley, Ahmed Bassiouni, John R. Scott, Yazeed A. Al Suliman, Jate Lumyongsatien, Stephen Moratti, Alkis J. Psaltis, Sarah Vreugde, and Peter-John Wormald.	2023	Yes	Yes
57	Comparison of the Efficacy of Ivalon® Nasal Pack and Ribbon Gauze Pack Following Nasal Surgeries-A Randomised Clinical Trial K Gowthame, S Prabakaran, RB Namasivaya Navin, and KARTHIKA RANGANATHAN4	2022	Yes	Yes

58	Comparison of Innovative Breathable Nasal Packs with BIPP Gauze Packs in Nasal Septum Surgery Raana Amir Akbar, Waqas Javaid, Muhammad Naeem, Mirza Muhammad Sarwar, Maryam Fatima, and Hira Andleeb	2022	Yes	Yes
59	Effect of chitosan-based gel dressing on wound infection, synechia, and granulations after endoscopic sinus surgery of nasal polyps: A meta-analysis Ruyang Liu and Zheng Gong	2022	Yes	Yes
60	Comparison of diferent oval window sealing materials in stapes surgery: systematic review and meta-analysis Alfonso Scarpa, Pasquale Marra, Massimo Ralli, Pasquale Viola, Federico Maria Gioacchini, Giuseppe Chiarella, Francesco Antonio Salzano, Pietro De Luca, Filippo Ricciardiello, Claudia Cassandro, and Grazia Maria Corbi	2022	Yes	Yes
61	Efficacy of Balloon Tamponade Versus Merocel Nasal Packs in Endoscopic Sinonasal Surgery: A Randomized Controlled Study Pradeep Pradhan, Chappity Preetam, Pradipta Kumar Parida	2022	Yes	Yes
62	Surgiflo® hemostatic matrix versus NasoPore® nasal packing following postassium titanyl phosphate laser surgery for hereditary hemorrhagic telangiectasia: A randomized controlled trial Justin M. Pyne MD, Scott Murray MD, Brendan C. Kelly MD, Jin Soo Song MD, Brandon R. Rosvall MD, David W. J. Côté MD	2023	Yes	Yes
63	Effect of esterified hyaluronic acid as middle ear packing in tympanoplasty for adhesive otitis media Rui Deng, Yanqing Fang, Jun Shen, Xiong Ou, Wenyi Liuyan, Bin Wan, Yasheng Yuan, Xiaoting Cheng, Yilai Shu & Bing Chen	2017	Yes	Yes

64	Hyaluronic Acid Gel as an Outer Ear Canal Packing Following Tympanoplasty: A Randomized Controlled Study Deniz Hanci, Semih Karaketir, Onur Ustun, Berk Gurpinar, Yavuz Uyar	2021	Yes	Yes
65	The Effect of PRP-enriched Gelfoam on Chronic Tympanic Membrane Perforation: A Double-blind Randomized Clinical Trial Masoumeh Saeedi, Mohammad Ajalloueian, Esmaeil Zare, Abolfazl Taheri, Jaleh Yousefi, Seyyed Mohammad Javad Mirlohi, Nasrin Mohammadi Aref, Mohammad Javid Saeedi, Mohammad Hossein Khosravi	2017	Yes	Yes
66	A safe and comparable alternative to BIPP packing following tympanoplasty for tympanic membrane perforation. Sheneen Meghji, Wahidah Wahid, Eyal Schechter, Codruta Neumann, Aaron Trinidade1	2020	Yes	Yes
67	Efficacy of middle-ear packing in success of type 1 tympanoplasty: a prospective randomised study S R Sahoo, J Tripathi, S Kumari and S Rastogi	2021	Yes	Yes
68	A pilot randomized controlled trial comparing bismuth iodine paraffin paste external ear pack and no ear pack after middle ear surgery Faisal Javed, Russell Whitwell, Daniel Hajioff, Philip Robinson, David Rea, Iain Macleod, Paul White, Desmond A. Nunez	2013	Yes	Yes
69	Effect of middle ear gelfoam on hearing and healing process after tympanoplasty: A prospective randomized case-control study	2021	Yes	Yes

	Jae Sang Han, Jung Ju Han, Yahya Dhafer AlAhmari, Jung Mee Park, Jae-Hyun Seo, So Young Park, Shi Nae Park			
70	Steroid Antibiotic Pack Versus 10% Ichthammol Glycerol Pack in Management of Acute Otitis Externa: A Comparative Study Akshaya Thrinetrapriya N, Nandhini R, Shoba K	2021	Yes	Yes
71	Comparison of functional outcomes of cartilage tympanoplasty with silastic sheet versus Gelfoam packing in middle ear Mahtab Rabbani Anaria , Amir Miratashi Yazdib , Elnaz Kazemia , Atie Moghtadaiec , Abolfazl Farbodd , Hamed Emamia,	2020	Yes	Yes
72	Comparison of clinical outcomes of three different packing materials in the treatment of severe acute otitis externa D Demir,MSYılmaz, M Güven, A Kara, H Elden and Ü Erkorkmaz	2017	Yes	Yes
73	A Comparative Study: Platelet-Rich Fibrin Packing as an Alternative to the Absorbable Gelatine in Tympanoplasty Goksel Turhal , Arin Ozturk , Tayfun Kirazli , Isa Kay	2022	Yes	Yes
74	Anterosuperior anchoring myringoplasty using cyanoacrylate glue can prevent packing gelfoam in the middle ear cavity Y. Li, J. Lianga, Y. Cheng, Q. Zhanga, X. Rena, Y. Shenga	2017	Yes	Yes

75	Does intraoperative ciprofloxacin-soaked gelfoam have adverse effects on graft success rate? A randomized, double-blind controlled trial Mohammad Faramarzi, Tayebeh Kazemi, Mahmoud Shishegar, Omid Zargerani, Ali Faramarzi, Tahereh Mohammadi, Fatemeh Kooreshnia, Saleh Aghaei, Mohammadali Asadi, and Amirhossein Babaei.	2021	Yes	Yes
76	Comparison of biodegradable synthetic polyurethane foam versus Gelfoam packing in cartilage graft myringoplasty procedures Zhengcai Lou	2020	Yes	Yes
77	The outcomes of endoscopic myringoplasty: packing with gelatin sponge versus packing with nothing Dan Wang , Tongli Ren and Wuqing Wang	2020	YES	YES
78	Platelet-Rich Fibrin (PRF): an autologous packing material for middle ear microsurgery P. Garin , Y. Peerbaccus , N. Mardyla , F. Mullier , D. Gheldof, Jean-Michel Dogne, L. Putz, and J.P. Van Damme	2014	Yes	Yes
79	Topical use of autologous platelet rich plasma in myringoplasty Mohammad Waheed El-Anwar, Magdy Abdalla Sayed El-Ahl, Amal Ahmad Zidan, Mohammad Abdel-Rhman Abdel-Salam Yacoup	2015	Yes	Yes
80	Open label, interventional, single arm multicentric clinical study to analyze the potency of VELNEZ nasal pack, post-nasal surgery Shama Bellad, Nagula Parusharam, Vineeta Dhyani, Pankaj Bablani and Siddharth Pandey	2023	Yes	Yes

Public domain data:

ADVERSE EVENT REPORT

Objectives:

To identify and evaluate the adverse event/product recall by collecting published events from the 4 major regulatory authority databases in MAUDE (Manufacturer and User Facility Device Experience), MHRA (Medicines and Healthcare products Regulatory Agency), TGA (Therapeutic Goods Administration) & Health Canada.

Search Strategy:

The adverse events/product recalls search was carried on through search engines in MHRA, TGA, MAUDE and HEALTH CANADA database.

Keywords used for the search

(1) Gelatin nasal sponge
(2) Chitosan nasal dressing
(3) "Nasal Dressing"
(4) "Nasal Pack"
(5) Septoplasty dressing
(6) "Sinus surgery dressing"
(7) Axiostat
(8) Meropack
(9) Gelspon p
(10) Gelfoam and "Nasal Pack"
(11) Nasopore
(12) Posisep X
(13) Rapid Rhino Nasastent
(14) MeroGel
(15) "Ear dressing"
(16) Surgispon
(17) Tympanoplasty Dressing
(18) Ear-pack and surgery
(19) Chitosan and ear
(20) "Myringoplasty dressing"
(21) Middle ear pack
(22) Otopore

Inclusion and Exclusion Criteria:

Inclusion Criteria: Reports/events/articles related to Sterile Haemostatic Absorbable Gelatin Sponge IP/USP within defined intended use.

Exclusion Criteria: Reports that not relevant to the device under evaluation.

Databases from which Characteristics have been searched:

(A) MAUDE Data base (Year 2012- 2022)
(B) MHRA (Year 2010-2022)
(C) TGA (Year 2010-2022)
(D) Health Canada (Year 2010-2022)

Database	Keywords	Cases reported	Usable Hits	Excluded Hits	Case relevant to Nasal/VelNez intended use	Hazard included in Risk analysis
MAUDE **Manufacturer and User Facility Device Experience – USFDA**	Gelatin nasal sponge	05	03	02	Physician reported that during a trans-nasal approach for a tumor in the mid brain, as he went to insert the gelfoam, it tore into pieces: he was unable to make the product perform against the bleeding.	No Based on the information available, direct, testable, forensic, empirical evidence was not provided to rule out that the device malfunctioned (including impact to the finished device) and the malfunction of the device or a similar device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur
					Only 01 Complications included postoperative cerebrospinal fluid (csf) leakage (n=6) which was treated with postponed removal of intranasal vaseline gauze and reducing intracranial pressure, wherein five of these patients were healed in 7 days; and delayed csf leakage (n=2) wherein the intranasal gauze was partially withdrawn to reduce compression on nasal mucosa and lumbar drainage was sustained until the leak disappeared 3 weeks later.	No Event was reported based on journal. In absence of sufficient data and on basis of DMPL clinical trials/literature study this incident was not covered.
					A female in her (b)(6) presenting with facial pain and sinus polyp was treated at (b)(6), using gelita-spon/invotec final as an ent adhesion barrier. At three weeks post-op follow-up, the patient was found to have developed adhesions between the middle turbinate and lateral nasal wall. Patient will return to the operating room for revision and division of these adhesions. The same surgeon reports a further two (recent) cases of adhesions after middle meatal antrostomies and ethmoidectomy. For these two events, no further patient details, event details or patient outcomes were provided by the surgeon when requested.	As per the characteristic of the device the device is self-fragmentable and the adhesion of the tissue is not possible with VelNez. Further irrigation with saline water is suggested as per requirement, mentioned in IFU.
	Chitosan nasal dressing	00	00	00	NA	NA
	"Nasal Dressing"	39	05	34	It was reported that, after a nasal surgery, the patient was complaining of a severe pain and headache. The "rapid rhino, dissolvable nasal dressing" was not dissolving after following hydration guidelines and trimming method.	No The complaint was not verified and the root cause could not be determined since the reported

					This issue was detected after nasal surgeries and no delays or other complications were reported.	malfunction could not be duplicated during the product evaluation process.
					It was reported that two 9 cm nasal dressings were improperly placed with the protective plastic sheath still in situ resulting in nasal mucosal damage and epistaxis. The patient was successfully treated (for nose bleed) and released on the same day. Subsequent recovery was uneventful.	No The root cause analysis was not performed by the manufacturer.
					It was reported, the merocel tube was not secured once patient went home. Just simply packed into his nose while at home before bed around approximately 12 am, the patient said it felt like the tubing was migrating inward so the wife pulled the tubing back some and assumed everything was fine and so they went to sleep. When they woke up, the tubing was gone and so they called dr. (b)(6), concerned that perhaps the patient could have swallowed the tube in his sleep. Dr. (b)(6) met with the patient, pulled the packing, and dissected the packing to search for the tubing which wasn't there. An x-ray was done, and it showed no evidence of the tube being swallowed. The doctor had the patient return home to look for the tubing but they couldn't find it. For now, the patient is fine and is to update the doctor, should his condition change.	No The root cause analysis was not performed by the manufacturer.
					It was reported that the patient swallowed a merocel sponge with string. The patient was x-rayed and the sponge was located. Multiple attempts to obtain additional information as to the status of the patient have gone unanswered.	No The root cause analysis was not performed by the manufacturer.
					It was reported that the patient had undergone a sinus procedure (septoplasty/turbinoplasty) and the dressing w/o string was placed without complication. The patient was taken to recovery and approximately 20-30 minutes later, the patient was reported to have aspirated the dressing and the dressing became stuck in the patient's carina and the patient asphyxiated. Cpr and emergency tracheotomy were performed, but neither could dislodge the dressing. The patient was transported by ambulance to the hospital whereby the patient expired.	No The device was discarded by the user facility; therefore, a product evaluation could not be conducted.
	"Nasal Pack"	84	09	75	It was reported that, after a severe epistaxis originating from the right nasal cavity, a rapid rhino nasal pack was used to control the bleeding. Patient stated extreme discomfort upon insertion of the pack. The rapid rhino was left overnight and deflated the next morning, shortly after experiencing right-sided rhinorrhoea after removal of the pack. Rhinorrhoea became more profuse as the day progressed. The liquid was tested and found to be cerebrospinal fluid (csf). A significant amount of trauma and swelling to the right nasal cavity was noted. Because of the severe congestion and lack of response to vasoconstriction the case was managed expectantly, pneumovax was administered. By the sixth day post-admission the rhinorrhea had resolved and no further complications were developed. A ct scan revealed a fractured right	No The root cause analysis was not performed by the manufacturer.

					middle turbinate, at its superior insertion to the skull base, which presumably happened upon initial insertion and inflation of the pack.	
					It was reported that the patient experienced nasal bleeding and anaemia. The patient received nasal packing, two units of packed red blood cells (pbrcs), and medication. The next day, bleeding occurred when attempting to remove the nasal packing. A bilateral nasal endoscopy was performed in the operating room (or) the following day with removal of the nasal packing. The ventricular assist device (vad) remains in use. No further patient complications have been reported as a result of this event.	No The root cause analysis was not performed by the manufacturer.
					Patient underwent bilateral total ethmoidectomy and maxillary antrostomy during which bilateral steroid-eluting sinus implants were placed in the ethmoid cavities. Bioresorbable nasal packing product was placed within the implant on each side. No polyps or infection were encountered during surgery. Blood loss was minimal and the surgery was uneventful. Postoperatively, the patient was on oral antibiotics for 10 days and twice daily saline irrigations. Postoperative appointments occurred weekly. The first two appointments were reported to be uneventful and included endoscopy and debridement, the implants were left in place. At the third postoperative appointment, the patient reported feeling poorly. The examining physician noted pus in the sinuses, worse on the right. Cultures were obtained and grew non-resistant staphylococcal species. The patient was started on augmentin. Subsequently, approximately 3 ½ weeks postoperatively, the patient presented to the emergency room and reportedly appeared toxic. A ct was obtained and showed diffuse inflammation in the operated sinuses, but no evidence of orbital wall dehiscence, or paranasal abscess formation. Blood cultures were obtained (eventually grew staphylococcal species), the patient was admitted and placed on iv antibiotics. The patient improved and discharged to home without further medical or surgical intervention.	No The root cause analysis was not performed by the manufacturer.

					It was reported that the patient underwent two prior fess procedures for allergic fungal sinusitis (afs) and polyposis. The patient also had a complex septal deviation. A third fess procedure for recurring afs and septoplasty was performed on (b)(6) 2015. Novashield nasal packing was used (1 syringe per nasal cavity). During the patient's post-operative appointment, it was observed that the novashield material was very gummy and very much like gorilla glue. The doctor reported the nasal packing as extremely tenacious and difficulty suctioning, resulting in multiple visits (5 minimum) with extended debridements and discomfort for patient. The patient was instructed to irrigate the sinuses with a saline spray along with tobramycin and steroid irrigations and although the packing began to loosen, the product was still not dissolving properly. The doctor decided to withhold the tobramycin as he was not sure if that was contributing the tenacity of the residual packing. The doctor later reported that he was able to remove most of the product without surgical intervention; however, at a later visit the patient was still experiencing discomfort. Utilizing a flex-scope, the doctor visualized product still remaining in the approximate region of the maxillary sinus. One-month post-op, on (b)(6) 2016, the patient was taken back to the or and a large amount of non-dissolved packing was removed. The patient will require treatment for crusting of healing mucosa.	No The root cause analysis was not performed by the manufacturer.
					It was reported that the novashield injectable nasal packing was used for a bilateral front ospheno ethmoidectomies with antrostomies. The physician reported that two weeks after the fess procedure, the patient experienced synechia (adhesion(s)) as well as poor drainage. The patient was prescribed saline irrigation and was compliant with the physician's instructions. Follow-up with the physician indicates that the patient is currently doing fine.	No The root cause analysis was not performed by the manufacturer.
					It was reported in the article the impact of different nasal packings on postoperative complications, am j otolaryngol head and neck med and surg (2014), that: * of 71 patients treated with merocel: 14 (19. 71%) had post-operative nasal synechia 8 (11. 26%) had septal perforation 3 (4. 22%) had post-operative infection (periorbital cellulites and rhinosinusitis) 2 (2. 81%) had epistaxis after removal of nasal packing in post-operative period (4 weeks) when compared with patients that had a nasal splint (n=59) the only parameter that was statistically significant was the nasal synechia (the nasal splints cohort had zero (0) nasal synechia).	No The root cause analysis was not performed by the manufacturer.
					It was reported the pt developed generalized urticaria following insertion of kaltostat nasal packing after functional endoscopic sinus surgery (fess) and septoplasty procedure. It was further reported the product was used at the end of the procedure and was in place approximately 3. 5 hours before developing symptoms. The kaltostat nasal packing was removed. Following	No The root cause analysis was not performed by the manufacturer.

					the procedure, the end user developed urticaria, hypotension and bradycardia and required overnight admission, med treatment and monitoring.	
					From the article published in the journal "otolaryngology -- head and neck surgery" 2012 entitled "an evaluation of biodegradable synthetic polyurethane foam in patients following septoplasty: a prospective randomized trial, by mahmut sinan yilmaz, mehmet guven, sultan sevik elicora, and recep kaymaz, md. Received July 5, 2012; revised September 17, 2012; accepted october 3, 2012. It was reported that the Medtronic merocel nasal packs (8 cm long in each nostril; pope epistaxis packing) was used after septoplasty procedures for 22 patients with nasal respiratory impairment caused by septal deviation. The merocel patients were only 1 of 3 groups in the study, which consisted of 13 males and 9 females ranging from 20-37 years in age. There were no septal hematomas, local infections, or severe bleeding requiring repacking in any of the patients. The merocel group had 7 patients with no bleeding, 5 patients with mild bleeding, and 10 patients with moderate bleeding after packing removal. For adhesions, there were a total of 7 patients with 5 developing mild adhesions, 1 developing a moderate adhesion, and 1 unspecified patient developed a severe adhesion where synechiae occurred. It was required for the patient who developed synechiae to undergo synechiolysis.	This device is used for therapeutic purposes. (b)(4). This device is being reported from a literature review. No devices will be returning. The device was not returned and therefore no evaluation could be performed. (b)(4).
					Pt had sinus surgery 4 years ago and nose was packed with dissolvable packing product was supposed to dissolve in a week but it took 30 days to dissolve. Pt stated during the 30 days he had difficulty breathing, could not sleep, and he developed a smell in his nose which he still has 4 years later. Pt has had antibiotics, CT scan done and doctor's unable to determine why he has a smell in his nose. He has been sick ever since surgery and diagnosis with depression.	No The root cause analysis was not performed by the manufacturer.
	Septoplasty dressing	07	03	04	It was reported that during a 6-week post-operative appointment, the patient presented with nasal pain and a strong odor following a septoplasty/ turbinoplasty procedure which involved a nasastent dressing. Upon examination, the surgeon detected signs of potential staph infection covering a large firm gel mass. The surgeon alleged that the gelled mass was the nasastent device, which did not appear to have dissolved over the 6-week period. The patient claimed to have followed the post-operative instructions of saline nasal washes 3 times per day for 6 weeks, however the patient did admit that the saline wash was prepared at home using boiled water and salt. Ultimately, the patient was treated with antibiotics for the infection. No additional patient complications have been reported.	No Saline used for irrigation was not sterilized that lead to the growth of infection.
					It was reported the pt developed generalized urticaria following insertion of kaltostat nasal packing after functional endoscopic sinus surgery (fess) and septoplasty procedure. It was further reported the product was used at the end of the procedure and was in place approximately 3. 5 hours before developing symptoms. The kaltostat nasal packing was removed. Following the	No

					procedure, the end user developed urticaria, hypotension and bradycardia and required overnight admission, med treatment and monitoring.	As per the characteristic of the device the device is self-fragmentable and the adhesion of the tissue is not possible with VelNez.
					It was reported that the patient had undergone a sinus procedure (septoplasty/turbinoplasty) and the dressing w/o string was placed without complication. The patient was taken to recovery and approximately 20-30 minutes later, the patient was reported to have aspirated the dressing and the dressing became stuck in the patient's carina and the patient asphyxiated. Cpr and emergency tracheotomy were performed, but neither could dislodge the dressing. The patient was transported by ambulance to the hospital whereby the patient expired. No further information was available from the user facility.	No The root cause analysis was not performed by the manufacturer.
	"Sinus surgery dressing"	01	00	01	NA	NA
	Axiostat	00	00	00	NA	NA
	Meropack	00	00	00	NA	NA
	Gelspon p	00	00	00	NA	NA
	Gelfoam and "Nasal Pack"	00	00	00	NA	NA
	Nasopore	31	10	21	It was reported that during a functional endoscopic sinus(fess) and polypectomy surgery, the patient experienced suspected laryngospasm requiring continuous positive airway pressure(cpap). It was further reported that the patient expectorated both large pieces of nasopore product via the mouth. It was also reported that the procedure was completed successfully.	No The root cause analysis was not performed by the manufacturer.
					It was reported that post operatively that the nasopore product did not fragment after the patient had irrigated the product with saline spray. It was further reported that there was no adverse consequence for the patient or delays to surgery as a result of the reported event. It was also reported that the surgery was completed successfully.	No No adverse consequence for patient was reported.
					It was reported that after a surgical procedure involving nasopore product, the patient returned to the hospital with alleged toxic shock syndrome it was further reported that the patient required additional medical treatment to address the toxic shock symptoms it was also reported that the patient was treated successfully.	No The root cause analysis was not performed by the manufacturer.

					It was reported that there was a potential sterility breach on the packaging of the device. It was also reported that it was noticed prior to the procedure. It was further reported that there was no delay or adverse consequences as a result of this event.	No The packaging development engineer concluded that the root cause for the open pack was undetermined. A device history record (dhr) review and retained sample testing of the packaging of this lot number was performed and all manufacturing specifications were met during the time of manufacture of this product. Nasopore product IFU contains the note; "do not use if the package is open or damaged. ".
					It was reported post operatively, it was noted that the nasopore product was inhaled into the lungs of the patient in recovery. It was also reported a bronchoscopy procedure was required to remove the nasopore product from the patients' lungs. It was further reported that there was no delay reported and the procedure was completed successfully.	No The root cause analysis was not performed by the manufacturer.
					The customer reported via the sales rep that that after performing nasal surgery, the customer used nasopore forte. It was also reported that the patient returned to hospital 3 days later with pain and was reportedly diagnosed with an infection in the nasal cavity. It was further reported that the patient was prescribed antibiotics. It was also reported that all the packaging was discarded and that the lot/serial number and the part number is unknown. The customer further reported that this nasopore forte was part of the same batch as used in a previous complaint, however this cannot be confirmed.	No The root cause analysis was not performed by the manufacturer.
					It was reported that the nasopore packing had not dissolved a week after insertion. It was also reported that the patient suffered severe headaches. The product was suctioned out by the surgeon. There was no medical intervention or surgical delay reported as a result of this event.	No The quality investigation was completed by manufacturer and product was discarded.
					It was reported that post operatively, it was noted 7 to 10 days post insertion that the patient presented with a nasal infection. It was further reported that the product had not disintegrated as expected. It was also reported that the procedure was completed successfully.	No The root cause analysis was not performed by the manufacturer.
					It was reported that there was a potential sterility breach on the product packaging detected prior to use. It was also reported that this event did not occur during a surgical procedure, and there was no delay or adverse consequences as a result of this event	No The root cause analysis was not performed by the manufacturer.
					It was reported that prior to the surgical procedure, a hair in the pack was observed. It was also reported that this event did not occur during a surgical procedure, and there was no patient involvement or adverse consequences as a result of this event.	No The root cause analysis was not performed by the manufacturer
	Posisep X	01	01	00	A trial of a new product that had shellfish ingredients (internal nasal sinus surgery dressing/foam) was applied after the surgery was done as per	No

					instructions from the doctor. No one was aware the product had shellfish product until after the surgery was completed. Patient is allergic to shellfish. The vendor, gyrus acmi, notified dr. After the surgery was done that the trial product has small amounts of shellfish derivative in it. Dr immediately returned to o. R. To remove the packaging. The patient had no symptoms or signs of allergic reaction during his stay. The patient was monitored and observed per doctor's orders then discharged home. This packaging comes in a container with five individual packs. The complaint from the staff was they did not know the product contained shellfish derivatives. After conferring with the manufacturer, it was discovered the packaging did indicate it had shellfish derivatives, but it is hard to find on the packaging. The suggestion is this caution needs to be more visual.	As per composition we are not using shellfish ingredients.
	Rapid Rhino Nasastent	05	00	05	NA	NA
MHRA **Medicines and Healthcare products Regulatory Agency – UK**	Gelatin nasal sponge	03	00	03	NA	NA
	Chitosan nasal dressing	03	00	03	NA	NA
	"Nasal Dressing"	00	00	00	NA	NA
	"Nasal Pack"	00	00	00	NA	NA
	Septoplasty dressing	00	00	00	NA	NA
	"Sinus surgery dressing"	07	00	07	NA	NA
	Axiostat	00	00	00	NA	NA
	Meropack	00	00	00	NA	NA
	Gelspon p	11	00	11	NA	NA

	Gelfoam and "Nasal Pack"	11	00	11	NA	NA
	Nasopore	00	00	00	NA	NA
	Posisep X	02	00	02	NA	NA
	Rapid Rhino Nasastent	06	00	06	NA	NA
TGA **Therapeutics and Goods Administration – Australia**	Gelatin nasal sponge	00	00	00	NA	NA
	Chitosan nasal dressing	00	00	00	NA	NA
	"Nasal Dressing"	00	00	00	NA	NA
	"Nasal Pack"	00	00	00	NA	NA
	Septoplasty dressing	00	00	00	NA	NA
	"Sinus surgery dressing"	00	00	00	NA	NA
	Axiostat	00	00	00	NA	NA
	Meropack	00	00	00	NA	NA
	Gelspon p	00	00	00	NA	NA
	Gelfoam and "Nasal Pack"	00	00	00	NA	NA
	Nasopore	01	01	00	The patient experienced some laryngospasm on extubation accompanied by desaturation and requiring continuous positive airway pressure (CPAP). On emergence, the patient expectorated both large pieces of the nasal dressings via the mouth.	No The root cause analysis was not performed by the manufacturer.

	Posisep X	00	00	00	NA	NA
	Rapid Rhino Nasastent	00	00	00	NA	NA
HEALTH CANADA **Health Department of the Government of Canada**	Gelatin nasal sponge	00	00	00	NA	NA
	Chitosan nasal dressing	00	00	00	NA	NA
	"Nasal Dressing"	00	00	00	NA	NA
	"Nasal Pack"	01	00	01	NA	NA
	Septoplasty dressing	00	00	00	NA	NA
	"Sinus surgery dressing"	00	00	00	NA	NA
	Axiostat	00	00	00	NA	NA
	Meropack	00	00	00	NA	NA
	Gelspon p	00	00	00	NA	NA
	Gelfoam and "Nasal Pack"	00	00	00	NA	NA
	Nasopore	00	00	00	NA	NA
	Posisep X	00	00	00	NA	NA
	Rapid Rhino Nasastent	00	00	00	NA	NA

DATABASE	Keywords	Cases reported	Usable Hits	Excluded Hits	Case relevant to Velnez intended use	Hazard included in Risk analysis
MAUDE Manufacturer and User Facility Device Experience –USFDA	"MeroGel"	00	00	00		.
	Ear dressing	00	00	00		
	SURGISPON	00	00	00		
	Tympanoplasty Dressing	00	00	00		
	Ear-pack and Surgery	00	00	00		
	Chitosan and Ear	00	00	00		
	Myringoplasty dressing	00	00	00		
	Middle ear pack	00	00	00		
	Otopore	01	01	00	Surgeon used otopore for an otitis media. When the patient came back to the surgeon for a regular follow-up visit the patient indicated he suffered from hearing loss which was treated during surgery by performing a chain reconstruction. It was suspected that the otopore had insufficiently degraded. The product was not received for further information and no information was received on lot number, surgery date etc. The event was communicated to the sales rep during a routine visit to the surgeon. As no new information will become available, this is both the initial and follow-up report.	No The root cause analysis was not performed by the manufacturer.
MHRA	"MeroGel"	00	00	10		
	Ear dressing	00	00	00		

Medicines and Healthcare products Regulatory Agency – UK	SURGISPON	00	00	00		
	Tympanoplasty Dressing	00	00	00		
	Ear-pack and Surgery	00	00	00		
	Chitosan and Ear	00	00	00		
	Myringoplasty dressing	00	00	00		
	Middle ear pack	00	00	00		
	Otopore	00	00	00		
TGA **Therapeutics and Goods Administration – Australia**	"MeroGel"	00	00	00		
	Ear dressing	00	00	00		
	SURGISPON	00	00	00		
	Tympanoplasty Dressing	00	00	00		
	Ear-pack and Surgery	00	00	00		
	Chitosan and Ear	00	00	00		
	Myringoplasty dressing	00	00	00		
	Middle ear pack	00	00	00		
	Otopore	00	00	00		
HEALTH CANADA	"MeroGel"	01	00	01		
	Ear dressing	00	00	00		

Health Department of the Government of Canada	SURGISPON	00	00	00		
	Tympanoplasty Dressing	00	00	00		
	Ear-pack and Surgery	00	00	00		
	Chitosan and Ear	00	00	00		
	Myringoplasty dressing	00	00	00		
	Middle ear pack	00	00	00		
	Otopore	00	00	00		

Annexure E: Reference to any standards applied

S.No.	Standard/Guidance no.	Standard/Guidance Name
1.	COMMISSION DIRECTIVE2003/32/EC	COMMISSION DIRECTIVE 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/ 42/EEC with respect to medicaldevices manufactured utilizing tissues of animal origin
2.	EU Regulation 722/2012	COMMISSION REGULATION (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilizing tissues of animal origin
3.	MDR 2017/745/EU	European Medical Device Regulation
4.	Drugs & Cosmetics Act and Rules	Drugs & Cosmetics Act 1940 and Rules 1945
5.	ISO 14971:2019	Medical devices - Application of risk management to medical devices.
6.	ISO 22442-1: 2020	Medical devices utilizing animal tissues and their derivatives –Part 1: Application of risk management
7.	ISO 22442-2:2020	Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling
8.	ISO 22442-3:2007	Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (ISO 22442-3:2007)
Quality Management System		
9.	ISO 9001: 2015	Quality management system
10.	ISO 13485:2016	Medical devices - Quality management systems – Requirements for regulatory purposes
11.	21CFR Part 820	21CFR PART 820—Quality System Regulation
Symbols and Information supplied by Manufacturer		
12.	ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied - Part 1: General requirements
13.	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer

Biocompatibility		
14.	ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
15.	ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
16.	ISO 10993 -6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)
17.	ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
18.	ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
Sterilization		
19.	ISO 11137-1:2006/Amd 1:2018	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices-Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137- 1:2006, including Amd 1:2018)
20.	ISO 11137-2:2013/Amd 1:2022	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose- Amendment 1 (ISO 11137-2:2013/Amd 1:2022)
Packaging and Validation		
21.	ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems andpackaging systems (ISO 11607-1:2019)
22.	ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
23.	ASTM F88 / F88M - 21	Standard Test Method for Seal Strength of Flexible BarrierMaterials
24.	ASTM F2054 / F2054M -13	Standard Test Method for Burst Testing of Flexible Package SealsUsing Internal Air Pressurization Within Restraining Plates
25.	ASTM F1929 - 15	Standard Test Method for Detecting Seal Leaks in Porous MedicalPackaging by Dye Penetration
Clinical Evaluation and Vigilance		
26.	MDDEV 2.12.2-1 Rev.8 2013	Medical devices vigilance system.
27.	MEDDEV 2.7.1 Rev.4 2016	Clinical Evaluation: A guide for manufacturers and notified bodies

28.	MEDDEV 2.12/2 rev.2 2012	Guidelines on Post Market clinical follow up
29.	MDCG 2020-7	Post Market clinical follow up (PMCF) Plan Template A Guidelines for Manufacturer and notifying bodies.
30.	MDCG 2022-21	Guidance on periodic safety update report (PSUR) according to regulation (EU) 2017/745 (MDR)
31.	ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice
Other		
32.	ISO 14644-1:2015	Clean room and associated control environment
33.	USP 40 <151> Pyrogen Test, 2017	Biological Tests - USP 40 <151> Pyrogen Test, 2017