INSTRUCTIONS FOR USE
VENUS SHELL™

Product Guide & User Manual

VENUS SHELL™ (*VS1)*

CE HeroSupport MD

 CAUTION - For US only: Investigational Device. Limited by Federal (or United States) law to investigational use.

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EU REP	QbD RepS BV Groenenborgerlaan 16 2610 Wilrijk Belgium

VENUS SHELL™ is a trademark of HeroSupport SA.

Contact details on Vigilance to competent authorities:

Switzerland	Swissmedic	https://www.swissmedic.ch/swissmedic/en/home/contacts/contact.html
Great Britain	MHRA	Manufacturer's Online Reporting Environment (MORE) (digital platform)
UK-Northern Ireland Only	The Medicines and Healthcare Products Regulatory Agency	tel: +44 20 3080 6000 10 S Colonnade, London E-mail: aic@mhra.gov.uk Web site: www.mhra.gov.uk
Germany	BfArM	https://www.bfarm.de/EN/Home/_node.html Or AIMDD, MDD - Dr. Ekkehard Stößlein - tel:+49 228 207 5384 Federal Institute for Drugs and Medical Devices Kurt Georg Kiesinger Allee 3, D - 53175 Bonn, fax:+49 228 207 5300 E-mail: medizinprodukte@bfarm.de
Ireland	Health Products Regulatory Authority	Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IE - Dublin 2 E-mail: devicesafety@hpra.ie
Belgium	FAMHP	Avenue Galilée – Galileelaan 5/03, 1210 Brussels MDR Vigilance: C. Driesmans tel: +32 2 528 4418

Malta	Malta Medicines Authority	Medical Devices Unit Medicines Authority Sir Temi Żammit Buildings, Malta Life Sciences Park San Ġwann SĠN 3000, Malta Tel: +356 2343 9000 E-mail: devices.medicinesauthority@gov.mt

Any serious incident that has occurred in relation to the VENUS SHELL™ should be reported to the manufacturer and the competent authority of the Member State.

For the full list of competent authorities:
https://health.ec.europa.eu/document/download/900ad9e7-fc79-4617-93be-f6712a3e3306_en

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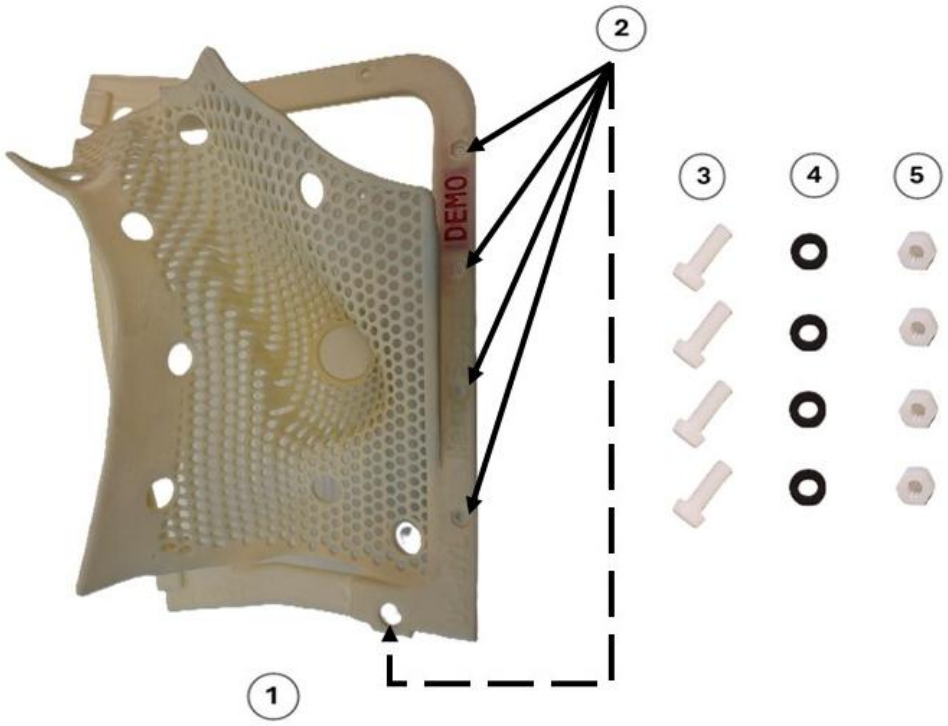
COMPONENTS OF THE VENUS SHELL™



1 VENUS SHELL™ – VS1

2 Four connection holes for attachment to the contralateral breast plate (CBP) of CDR Systems “ProCline advanced breast positioning system”. The fifth hole on the caudal edge of the frame is used to insert the lower pin of the CBP.

3 Plastic bolts (M6, polyamide) for connecting VENUS SHELL™ to contralateral breast plate of CDR’s ProCline system.

4 Rubber washer rings M6 to increase friction between nuts and bottom of contralateral breast plate.

5 Plastic fastening nuts (M6, polyamide).

INTENDED PURPOSE

The VENUS SHELL™ is intended to immobilize, position and reposition patients undergoing breast radiotherapy in prone position, including radiosurgery and photon treatments.

The VENUS SHELL™ can be used during image acquisition to support treatment planning.

The VENUS SHELL™ is MR-compatible.

DEVICE DESCRIPTION

The VENUS SHELL™ is a personalized 3D-printed breast device used to aid the immobilization, support and reposition patients during radiotherapy treatment sessions for breast cancer. The VENUS SHELL™ is made from biocompatible acrylonitrile butadiene styrene (ABS) using 3D-printing based on a 3D model of the patient's breast, arm and thorax region. The data for the VENUS SHELL™ is obtained via a patient model acquired using optical surface scanner imaging. When attached to a prone treatment table, it precisely positions and supports the patient's breast during radiation therapy or imaging. This process ensures accurate radiation delivery, thereby reducing exposure to healthy tissues and enhancing treatment effectiveness.

The VENUS SHELL™ is designed to come into direct contact with the patient's breast and surrounding skin of the torso.

The device is non-invasive, non-sterile, and single-patient reusable.

WARNINGS AND PRECAUTIONS

The VENUS SHELL™ is MR-compatible

⚠ WARNING

- Do not use it if the VENUS SHELL™ appears damaged or doesn't fit the patient anymore.
- Cutting or modifying the VENUS SHELL™ will affect its quality and render it unusable.
- Follow the instructions to correctly secure the VENUS SHELL™ to the prone treatment system using the dedicated bolts, rubber washers and nuts.
- The VENUS SHELL™ can only be used for the patient concerned throughout the set-up, imaging and treatment cycle.
- Before each use, make sure the VENUS SHELL™ fits the patient properly before installing and treating.
- The VENUS SHELL™ will attenuate a radiotherapy beam and increase skin dose. Attenuation and increased skin dose should be taken into account during planning and treatment.
- The VENUS SHELL™ may cause skin irritation in individuals with sensitive skin.
- The VENUS SHELL™ may only be used by qualified personnel, in accordance with the requirements of radiotherapy treatments.
- Do not sterilize the VENUS SHELL™.

DURATION OF USE

The VENUS SHELL™ should not exceed a cumulative use of 30 days.

The duration of use for one treatment should not exceed 1 hour.

EXPIRY DATE

The patient-specific VENUS SHELL™ is printed shortly after acquisition of the surface scan. To ensure proper matching with the patient's body shape, the VENUS SHELL™ should be used shortly after it was printed and only for the prescribed treatment. If the patient's body shape has changed noticeably (weight gain or loss, oedema, ...), it should be evaluated if the use of the VENUS SHELL™ is still appropriate for the treatment or if a new device must be produced. If properly stored (kept in a dry area and away from direct sunlight), the VENUS SHELL™ should not experience material degradation. It is recommended not to use the model after 3 months.

PATIENT AND USER INFORMATION

An electronic version of the IFU can be found on the website www.herosupport.care or requested per e-mail: info@herosupport.ch.

The instructions for use in electronic form shall be made available within 7 calendar days of receiving the user's request or at the time of delivery of the device if this was requested at the time of ordering.

If any serious incident occurs in relation to the VENUS SHELL™, the incident must be reported to the manufacturer. If an incident occurred within the European Union, also report it to the competent authority of the Member State in which you are established. See page 2 of the Instructions for Use.

SAFETY AND PERFORMANCE CHARACTERISTICS

Performance	Details
Immobilization	The VENUS SHELL™ immobilizes the breast during radiotherapy treatment, limiting unintended movement and maintaining a stable breast position throughout imaging and treatment delivery.
Positioning reproducibility	The VENUS SHELL™ provides a reproducible breast positioning during prone radiotherapy procedures with millimeter variability across sessions, supporting accurate patient setup and repositioning across imaging and treatment sessions.
Workflow efficiency	The VENUS SHELL™ improves clinical workflow efficiency by reducing the time required for patient positioning and pre-positioning compared to manual prone positioning without a

	dedicated immobilization device, while maintaining positioning accuracy and patient comfort.
Workflow integration	The VENUS SHELL™ integrates effectively into standard radiotherapy workflows without negatively impacting treatment planning or delivery.
Patient comfort	The VENUS SHELL™ supports the body around the breast and increases the patient comfort during use.
Reduced breast manipulation	The VENUS SHELL™ reduces the need for manual manipulation of the breast by medical staff during patient positioning and treatment setup, thereby improving staff comfort.

Safety	Details
Local Effects	Device-related adverse effects, such as skin irritation or discomfort, are expected to be infrequent, mild, and transient in nature, comparable with similar non-invasive radiotherapy immobilization devices.
Dosimetric considerations	With respect to dosimetric considerations, any increase in skin dose associated with the presence of the device is predictable, limited, and clinically acceptable within the context of prone breast radiotherapy, and comparable to effects reported for similar external immobilization or support devices.

Dosimetric Consideration

	6 MeV	10 MeV
Water equivalent thickness (10x10 cm^2 field size) 5 mm thickness mesh slab material	1.5 (mm H_2O equiv.)	1.9 (mm H2O equiv.)

Note: Use these values as a guidance only. Perform the measurements again in your department to verify these results.

UNPACKING AND INSPECTION OF THE VENUS SHELL™

⚠ WARNING

- Users of this product have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.
- Open packaging and handle the VENUS SHELL™ with care.
- Inspect the VENUS SHELL™ prior to use for signs of damage and general wear.
- In case of minor damage, check with HeroSupport if the VENUS SHELL™ can still be safely used. In case of major damage request a replacement from HeroSupport immediately.

1) Prepare the environment: ensure the unpacking area is clean, dry and free of contaminants.
2) Inspect the packaging: examine the outer packaging for visible damage (tears, dents, moisture, etc.). If any damage is observed, document it with photos and report it to the Quality Assurance department of HeroSupport at quality@herosupport.ch.
3) Open the packaging: carefully open the package without applying excessive force.
4) Unpack the VENUS SHELL™: remove the VENUS SHELL™ from the box and its plastic bag.
5) Verify Contents: check that the VENUS SHELL™ is intact and that its accessories (4 plastic bolts, 4 rubber washers and 4 nuts) are included in the package.
6) Visual inspection for damage: inspect for broken pieces, cracks, or deformations on the VENUS SHELL™. As shown in the examples below:

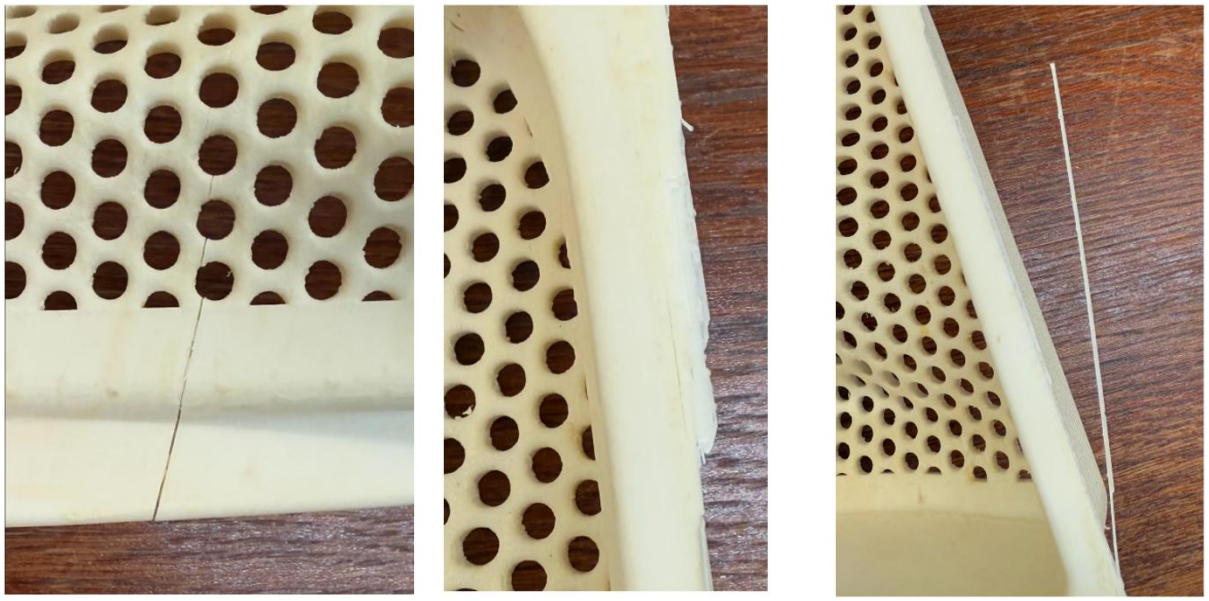


Figure 1 *Cracks and scratches examples*

NOTE: Any observed damage or irregularities must be reported immediately to the Quality Assurance (QA) of HeroSupport: quality@herosupport.ch. The device must not be used until it's cleared by HeroSupport or replaced with a new one.

IDENTIFICATION OF THE VENUS SHELL™

⚠ WARNING

- Ensure product labels, serial numbers, and compliance markings are intact and legible.

1) Verify the ID on the plastic bag corresponds to the ID on the frame of the VENUS SHELL™.
2) Verify that the Hospital ID marked on the frame of the VENUS SHELL™ matches your institution's assigned Hospital ID
3) Verify that the patient ID on the frame of the VENUS SHELL™ corresponds to the intended patient.

FIXATION OF THE VENUS SHELL™ ON THE PRONE TREATMENT TABLE

⚠ WARNING

- Only use the dedicated bolts, rubber washers and nuts to fix the VENUS SHELL™.

1) Align the holes on the VENUS SHELL™ with the mounting holes on the contralateral breast plate.
2) Fix the VENUS SHELL™ with the four dedicated bolts: Insert the bolts through the holes in the VENUS SHELL™ from top to bottom and lock them with a rubber washer and plastic nut, hand tighten, from below to the CBP.
3) Ensure the bolt has fully descended into its indentation in the VENUS SHELL™ frame. The top of the bolt must be aligned with the top of the frame or the top of the level indicators where present (see images below).
4) Place the contralateral breast plate with the attached VENUS SHELL™ between the lower and upper supports of CDR's ProCline system. To ensure identical positioning with the surface scan, use the HeroSupport transparent version of the cranial section.
5) Check that the VENUS SHELL™ fits properly between the two supports and the CBP is flat and touching on both supports.

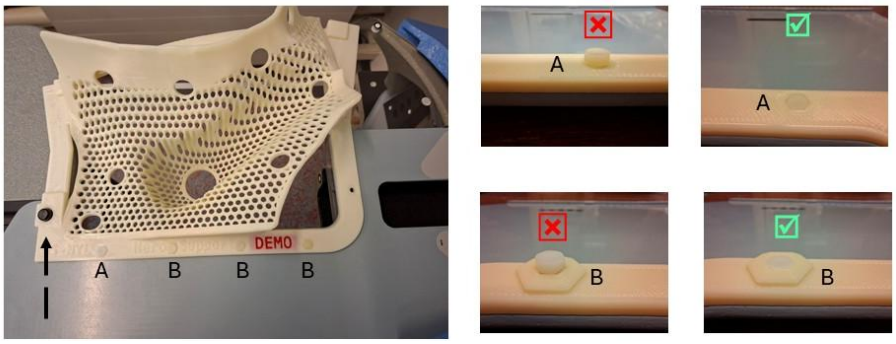


Figure 2 *Fixation of the shell to the contralateral breast plate (left) and position of the bolts and alignment with the top of the frame (right)*

INSTALLING THE PATIENT IN THE VENUS SHELL™

⚠ WARNING

- Patients are not allowed to put any weight on the CBP or VENUS SHELL™.
- Ensure the patient's safety during installation.

Follow the procedure below to position the patient correctly inside her VENUS SHELL™:

1) Follow CDR Systems ProCline prone breast-table's instructions to install the patient on the treatment table.
2) The patient should use her hands or elbows to bring her upper body into position, without leaning directly on the VENUS SHELL™ or the CBP.
3) The patient should lower herself slowly into position.
4) The patient should settle comfortably into the VENUS SHELL™ on her own.
5) Check that the patient's nipple projects into the middle of the VENUS SHELL™ opening.
6) Check that the patient feels no discomfort.
7) Visually check that the patient's body fits snugly around the VENUS SHELL™.
8) Visually check that the patient's body's surface is properly touching VENUS SHELL™'s inner surface at all the inspection windows (large round openings). Use a small mirror to visualize the less accessible windows.
9) If necessary, ask the patient to adjust her position.

To uninstall:

1) If necessary, assist the patient in removing herself from the VENUS SHELL™.
2) The patient should use her hands or elbows to withdraw slowly from the VENUS SHELL™, without leaning directly on the VENUS SHELL™ or CBP.

REMOVING THE VENUS SHELL™ FROM THE CONTRALATERAL BREAST PLATE

⚠ WARNING

- Be careful not to lose bolts, rubber washers and nuts.
- Handle the VENUS SHELL™ with care.
- Users of this product have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.
- If necessary, clean the surface of the VENUS SHELL™ by removing visual contaminants with hot water.
- Do not use any product containing Acetone (Ketones, Esters, Chlorinated hydrocarbons, Aromatic hydrocarbons, Alcohol, ...) on the VENUS SHELL™

1) Loosen nuts and remove the washers and bolts (push the bolts upwards).
2) Remove the VENUS SHELL™ from the contralateral breast plate.

PACKING THE VENUS SHELL™ IN ITS OWN PLASTIC BAG

⚠ WARNING

- Ensure the VENUS SHELL™ is protected in its own plastic bag.

1) Check that the ID on the product label on the plastic bag corresponds to the ID on the VENUS SHELL™.
2) Place the VENUS SHELL™ carefully in the bag.
3) Close the bag.

DISPOSAL OF THE VENUS SHELL™

The VENUS SHELL™ is a single-patient reusable device and should be disposed of after completion of the patient treatment. Dispose of the device in accordance with the local laws and regulations applicable to your country. The VENUS SHELL™ is made of ABS plastic (Acrylonitrile Butadiene Styrene), a recyclable material.

LIST OF SYMBOLS

	Manufacturer
	Date of manufacture
	Medical Device
	Unique Device Identifier
	CE Marking
	Consult instructions for use
	Caution
	Keep dry
	Keep away from sunlight
	Catalogue number (accompanied by the catalogue number)
	Use-by date (accompanied by the use-by date)
	Do not use if package is damaged and consult instructions for use
	MR conditional. The device has demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields. (ASTM F 2503-20)

EU REP	EU Authorized Representative
	Weblink