

Saint-Denis, le 23 avril 2007



Référence du document : DM-RECO 07/01

**DIRECTION DE L'ÉVALUATION
DES DISPOSITIFS MÉDICAUX**
Département des vigilances
DVI-DOC9

**A l'attention des directeurs d'établissement de
santé, des pharmaciens et des correspondants
locaux de matériovigilance pour diffusion aux
services concernés.**

MISE EN QUARANTAINE D'IMPLANTS FABRIQUES PAR LA SOCIÉTÉ SHELHIGH

M
A
T
E
R
I
O
V
I
G
I
L
A
N
C
E

Lors d'une inspection du centre de fabrication de la société Shelhigh, aux Etats-Unis, la FDA a mis en évidence des anomalies dans le processus de fabrication des dispositifs médicaux produits par cette société. Il existe notamment des doutes concernant la stérilité des produits, qui ont conduit la société Shelhigh à en cesser la mise sur le marché.

Par précaution, l'AFSSAPS vous demande, si vous détenez des dispositifs fabriqués par la société Shelhigh, de suspendre leur utilisation et de les mettre en quarantaine, sauf en cas de nécessité urgente et d'absence de solution alternative.

Les dispositifs fabriqués par cette société, et qui pourraient très prochainement faire l'objet d'un rappel, sont des implants utilisés notamment en chirurgie cardiaque, vasculaire, neurologique ; la liste des dispositifs concernés est la suivante :

- Shelhigh Pericardial Patch
- Shelhigh BioConduit stentless valve
- Shelhigh No-React Pericardial Patch
- Shelhigh No-React PneumoPledgets
- Shelhigh No-React VascuPatch
- Shelhigh No-React Tissue Repair Patch/UroPatch
- Shelhigh Pulmonic Valve Conduit No-React Treated
- Shelhigh No-React Dura Shield
- Shelhigh BioRing (annuloplasty ring)
- Shelhigh No-React EnCuff Patch
- Shelhigh No-React Stentless Valve Conduit
- Shelhigh Internal Mammary Artery
- Shelhigh Gold perforated patches
- Shelhigh Pre Curved Aortic Patch (Open)
- Shelhigh NR2000 SemiStented aortic tricuspid valve
- Shelhigh NR900A tricuspid valve
- Shelhigh MitroFast Mitral Valve Repair System
- Shelhigh BioMitral tricuspid valve
- Shelhigh Injectable Pulmonic Valve System

Nous vous demandons de communiquer à l'Afssaps – département de vigilance, fax 01 55 87 37 02 – toute éventuelle difficulté à trouver une solution alternative à l'utilisation de ces dispositifs.

NATIONAL COMPETENT AUTHORITY REPORT

For the exchange of information between device National Competent Authorities only

1. Is this report confidential? No [x]

Reference and Reporter Data

2. NCA report ref. no.: US-2007-04-18-013	3. Local NCA reference no.: na	4. Related NCA report nos.: (if any)
5. Manufacturer Ref/Recall no.: tbd	6. Sent by: D.Yoder/FDA	7. Contact person: See 6.
8. Tel: 240-276-3460	9. Fax: 240-276-3454 or -3501	10. E-mail: deborah.yoder@fda.hhs.gov

Device Data

11. Generic name/ kind of device: ALL DEVICES MADE BY SHELHIGH, INC		20. CAB/Notified Body no.:
12. Nomenclature id:	13. No.:	21a. Device approval status:
14. Trade Name and Model – see list and photos below		b. Risk Class:
15. Software version:		22. Action taken: <input type="checkbox"/> None <input type="checkbox"/> Recall <input type="checkbox"/> Safeguard Clause <input checked="" type="checkbox"/> Seizure
16. Serial no.: ALL	17. Lot/batch no.: ALL	
18. Manufacturer: Shelhigh, Inc., 650 Liberty Avenue Union, New Jersey 07083	19. Authorized rep (if different from 18): Country: Full Address: Contact: Tel: Fax: E-mail:	

Event Data

23a. Background information and reason for this. FDA's inspections at Shelhigh's US manufacturing facility revealed significant manufacturing problems that included improper sterilization and inappropriate extension of expiration dates for devices manufactured by Shelhigh, Inc. (650 Liberty Avenue, Union, New Jersey 07083). **ALL** medical devices manufactured by the firm could potentially be contaminated and may malfunction.

Please review the following web postings for all the information that is currently available:

The FDA posting about the seizure of Shelhigh devices is available at:

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01612.html>

The FDA public health notice related to Shelhigh devices is available at:

<http://www.fda.gov/cdrh/safety/041807-shelhigh.html>

The FDA patient advice notice related to Shelhigh devices is available at:

<http://www.fda.gov/cdrh/medicaldevicesafety/atp/041807-shelhigh.html>

24. Conclusions : FYI

• 25a. Recommendation to receivers of this report: Please see attached notifications for recommendations

25b. Device known to be in the market in- **US and Europe, and could also be anywhere in the world.**

25c. Device also marketed as (trade name):

Report Distribution

26. This report is being distributed to the NCAR Secretariat for further distribution to NCAR participants.

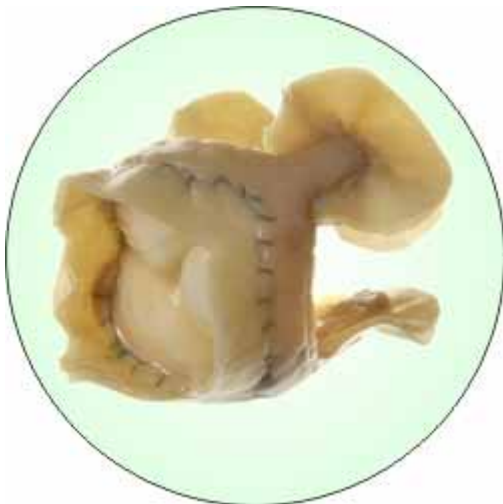
This NCAR applies to ALL products made by Shelhigh, Inc., 650 Liberty Avenue, Union, New Jersey 07083. The Shelhigh address is believed to be consistently displayed on the device packaging. Below are some known brand names of medical devices manufactured by Shelhigh, Inc., including those that have not been cleared by FDA:

- Shelhigh BioConduit™ stentless valve
- Shelhigh BioMitral™ tricuspid valve
- Shelhigh BioRing™ (annuloplasty ring)
- Shelhigh Gold™ perforated patches

- Shelhigh Injectable Pulmonic Valve System
- Shelhigh Internal Mammary Artery
- Shelhigh MitroFast® Mitral Valve Repair System
- Shelhigh No-React® Dura Shield
- Shelhigh No-React® EnCuff Patch
- Shelhigh No-React® Pericardial Patch
- Shelhigh No-React® PneumoPledgets
- Shelhigh No-React® VascuPatch
- Shelhigh No-React® Stentless Valve Conduit
- Shelhigh No-React® Tissue Repair Patch/UroPatch™
- Shelhigh NR2000 SemiStented™ aortic tricuspid valve
- Shelhigh NR900A tricuspid valve
- Shelhigh Pericardial Patch
- Shelhigh Pre Curved Aortic Patch (Open)
- Shelhigh Pulmonic Valve Conduit No-React® Treated

To facilitate a general appreciation of the variety of Shelhigh devices involved, I've copied pictures and descriptions from the Shelhigh website and pasted them below. These are only some of the devices made and distributed by Shelhigh.

Aortic:



The NR2000Plus SemiStented™ aortic tricuspid valve offers the benefits of a stentless valve but with the ease of implantation of a stented valve.

- A scalloped sewing hem offers a unique *self-pledgeted* implantation technique designed to reduce pannus formation and thereby optimize blood flow.
- No-React treated tissue resists calcification, degradation and infection even in cases of infective endocarditis.
- Porcine cusps provide natural valve operation with excellent hemodynamics.

cleared by: 



Lateral View of the Self-Pledgeted SemiStented Valve

To view a brief animation that demonstrates the self-pledged technique, click on the appropriate link below and your video viewer will start playing automatically.

[Medium resolution](#) (RealPlayer)

[High resolution](#) (Windows Media Player)

Note: The files above and below are streaming video, and several moments will pass before the video begins playing, depending upon your Web/network connection speed and your computer configuration.

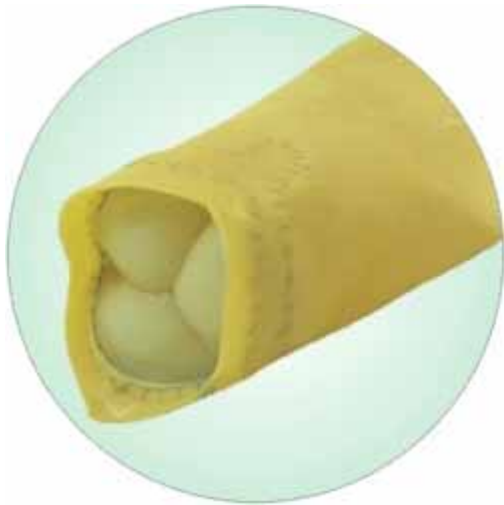
The NR2000 stentless aortic valves offers quick and easy supravalvular implantation using single layer continuous suture line.

- No need for rinsing and available in a wide range of off-the-shelf sizes.
 - No-React treated tissue resists calcification, degradation and infection even in cases of infective endocarditis.
-



- Porcine cusps provide natural valve operation with excellent hemodynamics.

cleared by: 



The BioConduit™ stentless valve conduit is an ideal device for use in the Bentall Procedure.

- Handles well and easy to implant.
- No suture holes; offers easy hemostasis.
- No-React treated tissue resists calcification, degradation and infection even in cases of infective endocarditis.
- Porcine cusps provide natural valve operation with excellent hemodynamics.

cleared by: 



The Shelhigh NR900A tricuspid valve is an ideal solution in cases of endocarditis.

- A wide sewing hem offers an ideal platform for the severely degraded patient annulus.
- No-React treated tissue resists calcification, degradation and infection even in cases of infective endocarditis.
- Porcine cusps provide natural valve operation with excellent hemodynamics.

cleared by: 

Mitral



The new MitroFast® Mitral Valve Repair System offers an innovative solution to the problem of mitral valve regurgitation.

- A system repair approach that includes the MitroFast® device and functional sizers (shown left)
- Functional sizers enable the surgeon to test the outcome of the repair prior to committing to the surgery.
- Simplifies the *art* of mitral valve repair through a process-driven approach.
- In clinical use since 2004.
- No-React® treated tissue resists calcification, degradation and infection.

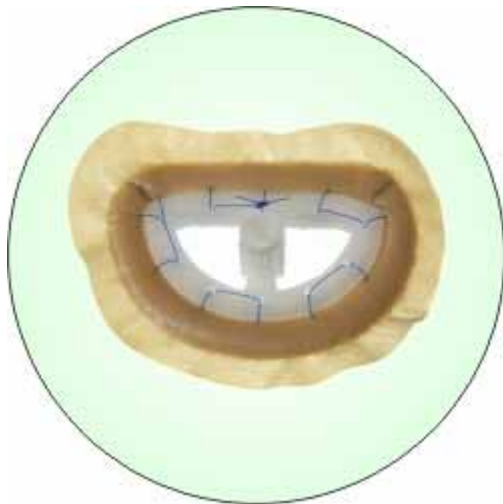
cleared by: 



The Shelhigh BioMitral™ tricuspid valve is an ideal solution in cases of infective endocarditis.

- No-React® treated tissue resists calcification, degradation and infection even in cases of infective endocarditis.
- Porcine cusps provide natural valve operation with excellent hemodynamics.
- A wide sewing hem offers an ideal platform for the severely degraded patient annulus.

cleared by: 



The BioRing® annuloplasty ring offers reliable repair support without exposure to non-biological materials.

- Totally biological and totally biocompatible.
- Available in bovine* and porcine tissue.
- A unique sewing hem that permits covering of the suture line with No-React® tissue in order to reduce hemolysis.

cleared by: 

*bovine tissue is cleared by the FDA

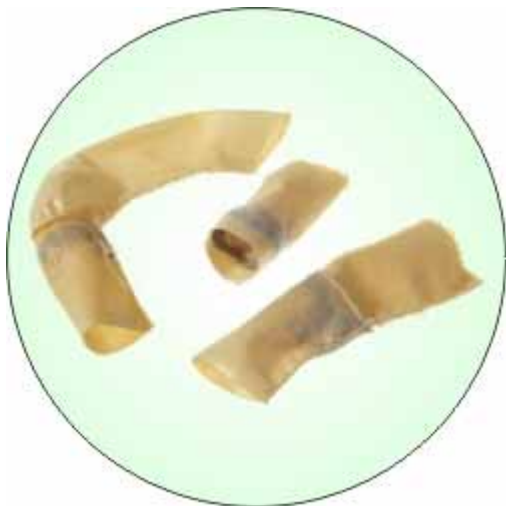
Pulmonic



The Shelhigh Injectable Pulmonic Valve System provides a truly innovative approach to pulmonic valve repairs.

- Installs in minutes and does not require cardiopulmonary bypass.
- The stented valve is injected directly into position through a small incision in the ventricle.
- Valve size is not restricted as with transcatheter methods.
- External fixation design helps prevent valve migration.
- Immediate and excellent hemodynamic results.
- In clinical use since 2004.
- No-React[®] treated tissue resists calcification, degradation and dilation.

cleared by: 



Shelhigh Pulmonic Valved Conduits have over 9 years of proven performance in the challenging pediatric population*.

- No-React[®] treated tissue resists calcification, degradation and dilation.
- An excellent alternative to a homograft
- Supple and easy to handle and suture.
- High suture pull strength.
- Available in both bovine and porcine tissue.

*Data is available on file.

cleared by:  

Patches



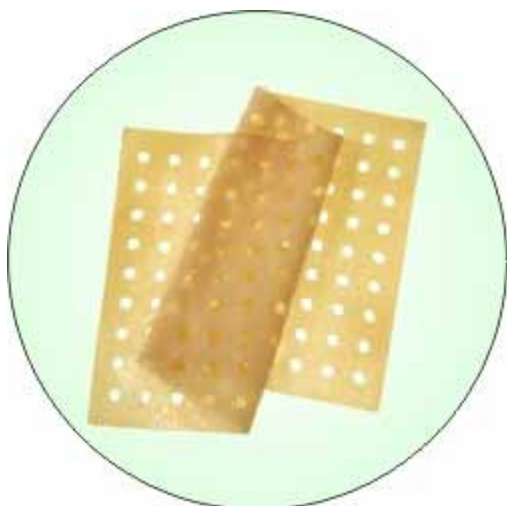
Shelhigh Patches are ideal for general surgical use and for cardiothoracic procedures.

- No-React[®] treated tissue resists degradation, dilation and calcification.
- Supple and easy to handle and suture.
- High suture pull strength.
- Available in both bovine and porcine tissue.

cleared by:



Closed Herd bovine
tissue*:



Shelhigh Gold[™] perforated patches are specifically designed for hernia repair.

- No-React[®] treated tissue resists degradation, dilation and calcification.
- Supple and easy to handle and suture.
- High suture pull strength.
- Available in bovine tissue.

cleared by:



Shelhigh products may be sold only upon the written prescription of a physician. Not all Shelhigh products are for sale in the United States; consult your Shelhigh distributor or Shelhigh Corporate Office for more information.

Shelhigh, Inc. | 650 Liberty Avenue | Union, NJ 07083 | 908-206-8706 | info@shelhigh.com