STARSIL® HEMOSTAT IN CARDIAC SURGERY - CUMULATIVE RESULTS

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StarSil Hemostat is manufactured from a purified plant-based polysaccharide. It consists of spherical particles (40-150 \(\mu m\)) with a large microporous surface.

The hemostatic effect of the powder is produced by the rapid dehydration and subsequent hemo-concentration of blood.

The concentration of red blood cells, platelets, and serum proteins produces a gelled matrix. The surface of the gelled matrix stimulates the clotting cascade.

Normal platelet activation and fibrin deposition within the gelled matrix then produces a clot that limits further bleeding.

Complete absorption is achieved within approx. 2 days (degrading by endogenous alpha-amylase).
Mode of Action

- Engineered microporous particles
- Controlled pore size acts as a molecular sieve designed to gel blood and accelerate clotting
- Spherical, flowable beads with nominal size of 150 microns (99.2%)
- Proprietary process for resorbability
- In tests of 100 samples, Starsil absorbs on average 64ml H₂O/2g Starsil powder
Mode of Action

Scanning Electron Micrograph: Mesh of Starsil® Hemostat and coagulation proteins, RBCs, platelets and other blood components
Introduction

Content of the box
Introduction

no special storage

ready to use

broad field hemostatic agent

multiple surgical disciplines
Step 1

Break and remove cap
Application Technique

Step 2

Remove excessive blood with a gauze

1= gauze, 2= blood, 3= wound
Step 3  Application of powder to the source of bleeding
Application Technique

Step 4+5  After moderate compression rinsing with water
Result: Gel formation and hemostasis
Time of Degradation

StarSil® Hemostat and other hemostatic adjuncts*:

- **StarSil®** Polysaccharide Hemostat: 48-72 h
- Gelatin matrix: 4-6 weeks* (e.g., Gelfoam® / Surgifoam®)
- Oxidized cellulose (ORC): 1-2 weeks* (e.g., Surgicel® / Tampontap®)
- Collagen matrix: 8-10 weeks* (e.g., INSTAT® / Avitene®)
- Bone wax: not absorbable

* Informations of the manufacturers and/or literature
## Cumulative Results of the Study: Starsil® Hemostat in Cardiac Surgery

### Demographic characteristics

<table>
<thead>
<tr>
<th>Patients</th>
<th>164</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (m/f)</td>
<td>102/62</td>
</tr>
<tr>
<td>Age years (yrs; mean±S.D.)</td>
<td>67±7</td>
</tr>
<tr>
<td>Anticoagulation therapy (n; %)</td>
<td>96 (58.5%)</td>
</tr>
<tr>
<td>(ASA, coumadines or dual platelet therapy)</td>
<td></td>
</tr>
<tr>
<td>Follow up (months):</td>
<td>6-18</td>
</tr>
</tbody>
</table>

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**Surgeons:** Prof. Dr. C. Schmitz, Prof. Dr. R. Sodian, Dr. H. Mair  
**Setting:** Cardiac Surgery, University of Munich, Munich Germany,  
Cardiac Surgery of Rinecker Clinic, Teaching Hospital of the University of Munich, Germany
Cumulative Results of the Study: Starsil® Hemostat in Cardiac Surgery

<table>
<thead>
<tr>
<th>Procedures performed (n):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CABG (on- and off-pump)</td>
<td>89</td>
</tr>
<tr>
<td>Valve procedure (+CABG)</td>
<td>31 (5)</td>
</tr>
<tr>
<td>Pacemaker/ ICD implantation</td>
<td>23</td>
</tr>
<tr>
<td>Aortic Replacement (+valve/CABG)</td>
<td>11 (9/3)</td>
</tr>
<tr>
<td>Heart transplant</td>
<td>2</td>
</tr>
<tr>
<td>Cardiac assist devices</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
</tr>
</tbody>
</table>

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Starsil® Hemostat in Cardiac Surgery
Intraoperative Results:

Starsil applied (5g units): 1,6+/- 0,8 (1-5 units)

Satisfaction with bleeding control:

- With first application (n/%): 152 92,7%
- With additional applications (n/%): 159 97,0%

Result of VAS 1-10 (visual analogue scale)* 8.2±1.5

In 5 (3%) pts the surgeons needed in addition other treatments for hemostasis (additional sutures in 4, other hemostas in 1 pt).

* Description of VAS-rating: VAS ranges from VAS =1 (no good performance) up to 10 (very good performance); VAS ≥ 7,5 means good to very good result.
### Adverse events (bleeding or wound infection):

<table>
<thead>
<tr>
<th>Event</th>
<th>Patients</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest reopening</td>
<td>4 patients (2.4%)</td>
<td>(all on dual platelet or coumadin therapy perioperatively)</td>
</tr>
<tr>
<td>- surgical bleeding</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>- diffuse bleeding</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
| Sternal wound infection      | 4 patients (2.4%) | 2 VAC therapy and refixation  
|                              |          | 2 VAC therapy only                                                      |
| Wound infection              | 5 patients (3.0%) | VAC therapy/normal dressing    |
Cumulative Results of the Study: Starsil® Hemostat in Cardiac Surgery

Adverse Events (product related):

- Product related deep sternal wound infection: 0
- Product related allergies: 0
- Product related sepsis: 0
- Product related shock: 0
- Product related embolism: 0
- Product related graft failure: 0
- Product related death: 0
Schmitz and Sodian do not contain any allo- or xenogenic additions. SIL® HEMOSTAT is biocompatible, non-pyrogenic and is achieved within approximately 48 to 72 hours. STAR- and limits further bleeding. Absorption of the particles produce a clot that functions as a mechanical barrier dened. Normal platelet activation and fibrin deposition ting cascade. As a result a gelled adhesive matrix is pro-

COPD: chronic obstructive pulmonary disease; BMI: body mass index; for grafting; RITA: right internal thoracic artery; LITA: left internal thoracic artery; Platelet inhibition

BMI > 30 (n) 6
Severe osteoporosis (n) 9
COPD (n) 14

Table 1 Demographic data of patients receiving STARSIL®

Figure 1

Figure 2. Sternum was closed with sternal wires, sub-

Towels were wrapped around the sternum for atraumatic ap-

Directly after sternotomy STARSIL® HEMOSTAT was ap-

standard techniques trying to use electrocautery sparingly.

Skin incision and median sternotomy were performed with

No adverse events or allergic reactions were observed

after median sternotomy.

Table 2 Intra- and postoperative results of patients

Satisfactory bleeding control (n) 37 (97%)

Hemoglobin

Direct postop. (g/dL) 9.1 ± 1.8

Cell saver (ml) 360 ± 210

VAS: visual analogue scale.

R.

Another interesting feature of starch-based hemostats

In our observation we had two different patient groups

There are some limitations that should be pointed out:

sternotomy patients were fully heparinized (activated

clotting time > 400 seconds) and open-heart surgery was

performed in a routine fashion. After graft placement

filters of blood salvage system, thus entering patient

store. The filters were used instead of the use of bone wax, the product remains in widespread use, pre-

absorbing large quantities of wax without hemostasis.

Furthermore, bone wax is often ineffective in elderly

patients at a high risk for infection or nonunion [6].

bone wax for control of sternal bleeding, especially in

wire extraction due to chest pain. All postoperative

re-administered six weeks postoperatively for sternal

procedure in which the wound was cleaned. Subsequently,

infections. The first patient required an outpatient pro-

treatment before insertion of the retractor. Bleeding

in the VAS was 8.4 ± 1.4 (Table 2).

One additional patients showed persistent bleeding requiring

re-application of the hemostat led to satisfactory results. The two

37 cases (97%). In all but two patients a single applica-

tion was necessary. No patient required sternal re-fixation due to

graft alteration, bleeding or unstable sternum were ne-

hospital mortality or product related morbidity observed

during the study period. There were no cases of in-

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Polysaccharide Technology for Bleeding Control

Minimal Invasive Aortic Valve Replacement via upper partial sternotomy

Starsil Hemostat was used for bleeding control at the sternum and round the aortotomy
Polysaccharide Technology for Bleeding Control

Bentalls Procedure: Replacement of the ascending aorta and the aortic valve with a conduit after dissection

Starsil® Hemostat was used for bleeding control at the suture lines of the conduit and the native tissue
Polysaccharide Technology for Bleeding Control

Replacement of the ascending aorta for repair of aortic aneurysm

Starsil® Hemostat was used for bleeding control at the suture lines and the native tissue.
Polysaccharide Technology for Bleeding Control

Coronary Arterial Bypass Grafts

CABG (off-pump)  Re-CABG (on-pump)

Starsil® Hemostat was used for bleeding control at the central and peripheral anastomoses of the grafts
Starsil® Hemostat was used for bleeding control at the central and peripheral anastomoses as well as for venous (left picture) or arterial grafts (right picture; thoracic artery- or radial artery grafts)
Polysaccharide Technology for Bleeding Control

Pacemaker and Defibrillator (ICD) Implantation

Starsil® Hemostat was used for bleeding control of the pacemaker and ICD pocket
Polysaccharide Technology for Bleeding Control

Venous and Arterial Bypass Graft Harvesting

v. saphena magna, right leg

a. radialis, left arm

Starsil® Hemostat was used for bleeding to prevent hematoma. After the CABG-procedure the patients receive dual platelet inhibition.
Conclusion

High hemostatic competence of StarSil® Hemostat

- Effective in diffuse or profuse bleeding with all tissue types
- Effective in patients under anticoagulation
- StarSil belongs to „second generation“ of plant based polysaccharide hemostats.
- StarSil is a „ready to use“-products. There is no additional step for preparation. Its use is simple and safe.
- There are no special regulations for storage.
- The mode of action is rapid.