PREVENTION OF
CARDIOVASCULAR AND THORACIC
SURGERY ADHESIONS

COVA+™ CARD
Resorbable guided-healing membrane
BIOMATERIAL DEVELOPED FOR THE PREVENTION OF POST-OPERATIVE ADHESIONS (1)
BIOCOMPATIBLE MEMBRANE

Acellular collagen
Patented COVA™ technology (1)

RESORBABLE

Resorption time adapted to the healing process (13 weeks) enabling it to play its barrier role (2, 3)

EXAMPLES OF SURGICAL INDICATIONS (4)

• Mitral insufficiency
• Hypoplasia
• Cardiac assistance

• Congenital pathology
• Valve replacement

(4) Instruction for use COVA+™.
POST-OPERATIVE ADHESIONS: RISKS TO BE CONSIDERED

- **RISKY REPEAT CARDIAC SURGERIES DUE TO THE PRESENCE OF ADHESIONS** (1)
  - Cause of potential complications (lacerations, hemorrhaging...)

- **POTENTIALLY LIFE-THREATENING ISSUES** (2)
  - Major risk noted in nearly 30% of cardiac reoperations with dense adhesions between large vessels and sternum (3)

- **POTENTIAL RISK OF LETHAL COMPLICATIONS WHEN ADHESIONS ARE RESECTED** (2, 4)
  - Up to 10% of cardiac lacerations noted during sternal re-entry (3, 5)
  - High mortality in case of “catastrophic hemorrhage” during cardiac reoperations (21%) (6)

- **MEDICAL OVERLOAD AND CONSIDERABLE EXCESS COSTS**
  - Average duration surgery is extended by approximately 15% (1)
  - Mean adhesion dissection time was = 165 ± 63 minutes

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(2) Haute Autorité de Santé, 2009.


Comparative assessment of the anti-adhesion performance of COVA+™CARD (1).

MATERIALS AND METHODS:
On sheep, creation of a pericardium defect and then placement of an adhesion-preventing membrane. Evaluation of safety and efficacy 4 months after implantation. Statistical comparison between COVA+™ CARD and two other anti-adhesion products (a resorbable membrane 1 and a non-resorbable membrane 2) and a control group (Student t-test).

RESULTS:
The COVA+™ CARD is easy to handle and repositionable. 4 months after implantation, the membrane is resorbed.

2010 study

With COVA+TM CARD, the adhesions are significantly less severe than membrane 2.

2012 study (3)

COVA+™ CARD generates significantly less inflammatory reaction than membrane 2 or control group.

COVA+™ CARD induces significantly less fibrosis than membrane 2 or control group.

HISTOLOGICAL FINDINGS (1):
H&E staining, original x 5.

The case of membrane COVA+™ CARD:
Histological section of the heart covered by a COVA+™ CARD membrane 4 months after implantation. On the left side, the myocardium is normal. The epicardium is normal without any sign of thickening or dense fibrosis.

The case of membrane 1:
Histological section of the heart covered by the resorbable anti-adhesion membrane. On the left side, the myocardium is normal. The epicardium is thickened by a dense and extensive fibrosis.
CLINICAL RESULTS AND EXAMPLES OF USE

Prospective study (*Update on the previously published study*) *(1)*
Pr Hénaïne, Hôpital Louis Pradel Bron

**MATERIALS AND METHODS:**
- Effectiveness and tolerance of the COVA+™ CARD membrane in pediatric heart surgery.
- Occurrence and severity of adhesions if re-entry in two at-risk areas: sternal and mediastinal area (ECC connection).
- 78 patients (average age 16 months), 30 re-entry surgeries
- Average time before reoperation: 192 days [1 – 558]
- Average duration of adhesion dissection: 26.2 ± 5.9 minutes

**RESULTS:**

<table>
<thead>
<tr>
<th>Sternal area</th>
<th>Mediastinal area</th>
</tr>
</thead>
<tbody>
<tr>
<td>90% grade 0</td>
<td>23% grade 1</td>
</tr>
<tr>
<td>10% grade 2</td>
<td>37% grade 0</td>
</tr>
<tr>
<td>23% grade 3</td>
<td>40% grade 1</td>
</tr>
</tbody>
</table>

Lodges adhesion scale (same as Heyden):
- Grade 0: no adhesions
- Grade 1: light adhesions easily lysed by digital dissection
- Grade 2: stronger adhesions, requiring tweezers for dissection
- Grade 3: dense adhesion, requiring sharp dissection

*Effectiveness:* no severe grade 3 adhesion in the two at-risk areas.
*Tolerance:* no complications due to adhesions on re-entry. No complications or reoperations due to any undesirable effects linked to the membrane.

**EXAMPLE OF A CLINICAL CASE IN PEDIATRICS:**
Pr R. Hénaïne, Hôpital Louis Pradel (Fr)

**EXAMPLE OF ADULT HEART SURGERY:**
Pr L. Barandon, Hôpital Haut Leveque 2013 (Fr)

- Implementation of a cardiac assist device with a femoro-femoral ECC.
- Wrapping the COVA+™ CARD membrane around the HeartMate II® pump.
- Blanketing the native heart and the HeartMate II® with COVA+™ CARD.

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*(2)* Instruction for use COVA+™.
COVA+™ CARD

PHYSICAL BARRIER BETWEEN THE HEART, LUNGS AND ADJACENT TISSUES

PREVENTS ADHESION, POTENTIAL SOURCE OF COMPLICATIONS
- Reduces frequency and severity of adhesions (1)
- Reduces fibrosis (2, 3, 4)
- Reduces inflammatory reactions (2, 3, 4)

FACILITATES ACCESS IN CASE OF REOPERATION
- Preserves cleavage and anatomical planes (2, 3)
- Simplifies* dissections to facilitate access to the operation site (2, 3)

MEETS PRACTITIONERS’ NEEDS
- Easy to handle and sturdy (1)
- Re-sizeable and re-positionable (5)

(1) Biom’Up, internal data.
(5) Instruction for use COVA+™.

* Reduces the formation and severity of adhesions.
**COVA+™ CARD**

**GUIDED-HEALING RESORBABLE MEMBRANE**

- **PREVENTS ADHESION AND RELATED COMPLICATIONS**
- **FACILITATES PATIENT REOPERATIONS**
- **EASY TO HANDLE AND STURDY**

**PACKAGING:**

COVA+™ CARD are individually double packaged units sterilized by irradiation.

<table>
<thead>
<tr>
<th>Sizes (mm)</th>
<th>150 x 200</th>
<th>100 x 150</th>
<th>80 x 120</th>
<th>60 x 80</th>
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<tr>
<td>References</td>
<td>COV+ 1520</td>
<td>COV+ 1015</td>
<td>COV+ 812</td>
<td>COV+ 68</td>
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LEGAL INFORMATION: COVA+™ - Implantable Medical Devices for surgery, reserved for use by qualified healthcare professionals, reimbursable under each country’s Social Security system. NOT FOR SALE IN THE USA. Read the instructions for use on the packaging carefully before use. CE 0086: BSI. Manufacturer: biom'up SA France. Photography: Ian Abella. Illustrations: Les Dalton, Shutterstock.