David Warwick’s Collagenase Information Sheet

**WHAT IS COLLAGENASE?**

Xiapex® is the trade name of collagenase clostridium histolyticum which is produced naturally from a bacterium called clostridium histolyticum. The drug was produced after many years of research leading to a clinical research programme which proved its effectiveness.

The drug specifically dissolves the collagen contained within a cord of Dupuytren’s Disease. This removes a segment of the cord. Once the segment is removed, the cord no longer tethers down the finger and so the finger can straighten. Until now, only surgery or needle puncture could achieve this. Xiapex can be considered as a “surgical drug”

In 2010 it was given approval by the FDA (Federal Drugs Administration) in the USA; in 2011, it was given approval by the European Medicines Agency and then by the UK.

The evidence which led to the approval by the FDA and European Medicines Agency can be seen below:


David Warwick has published further studies in 2015 to confirm the efficacy. Click on the hyperlink to see the results:


**What are the chances of being satisfied?**

In 587 patients given Xiapex, most patients (92%) were “very satisfied” (71%) or “quite satisfied” (21%) with treatment.


In 280 patients given Xiapex in nth Europe wide study published by David Warwick in 2015, the satisfaction rate was 87% at 6 months.


David Warwick has surveyed his patients for satisfaction in 2015.

**Results – overall satisfaction n=213**

Warwick D, Bradley J data on file

**Results – preference to surgery n=78/212**

<table>
<thead>
<tr>
<th>Participant preference for Xiapex over surgery</th>
<th>Definitely</th>
<th>Probably</th>
<th>Not sure</th>
<th>Probably not</th>
<th>Definitely not</th>
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<tbody>
<tr>
<td>Percentage</td>
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<td>24%</td>
<td>14%</td>
<td>8%</td>
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Warwick D, Bradley J data on file
**What are the chances of the disease coming back?**

The latest research shows that the chance of recurrence is high as the years go by especially in the PIP joint.

This means that the disease is quite likely to recur over time and if so satisfaction may decline. Treatment should be straightforward though, with another simple injection or if the disease is too troublesome then standard surgery.

**David Warwick's personal results**

See the RESULTS tab on the [www.collagenase.co.uk](http://www.collagenase.co.uk) website

**What happens when I have Xiapex®?**

You are assessed in the clinic by Professor Warwick to ensure you are suitable. The deformity of your fingers is measured and you are asked to fill out two brief questionnaires to assess your function.

On the day of the injection, you are asked to sign a consent form (downloadable in advance). The Xiapex is removed from the Pharmacy fridge an hour before the injection and warms up to room temperature. The two vials (fluid and powder)
and then gently mixed. Your hand is sterilised with alcohol and the Xiapex is injected into the cord with a very fine needle. A cold spray is used to minimise the discomfort. A dressing is applied.

Overnight, your hand may get quite bruised and swollen – that is normal and sometimes quite alarming.

On a convenient day within 7 days of the injection you come back for the manipulation. Your hand is sterilised again with alcohol. Local anaesthetic is injected around the cord (which can be quite sore) and then the cord is gently manipulated into extension until it snaps.

**CAN I DRIVE OR WORK AFTER THE INJECTION?**

You should not drive after the injection or manipulation until you feel safe to control the car in all eventualities. Choosing to drive is your own responsibility and not the Doctor’s. However, most people can drive within a few days.

With regards to return to work, the mean return to work is 4 days (Warwick et al 2015). This compares with 4 to 6 weeks for clerical work and 9 weeks for manual work with surgery. (Tonkin MA, Burke FD, Varian JPW (1984) Dupuytren’s Contracture: A Comparative Study of Fasciectomy and Dermofasciectomy in One Hundred Patients. Journal of Hand Surgery 9: 156)

**WHAT ARE THE COSTS?**

**Insured patients:** The insurance companies have applied a code to Xiapex injection: T7440, AC100 – Injection into cord for Dupuytren’s Contracture, W9240- manipulation under local anaesthetic

**Self funding patients:** At the Wessex Nuffield Hospital, there is a fixed price option (currently £1850) to cover the cost of a Xiapex injection including the drug, hospital tariff, surgeon’s fee and splint. If the injection does not work first time, then you would need to pay for the second at a similar rate. An initial consultation with Professor Warwick to see whether you are suitable is £180.

**ARE THERE RISKS?**

David Warwick’s personal complication rates are published on the Results Tab (www.collagenase.co.uk). There are two potential very serious, but very rare, problems:

- **Allergic reaction:** About 17% of people may have a mild allergic reaction – itching or a rash. The armpit nodes may become sore and swollen. There is a theoretical risk of anaphylactic shock (ie sudden collapse with airway obstruction and circulatory collapse). This is exceedingly unlikely and has never been reported with the drug. Nevertheless, Adrenaline (the antidote to this) is kept immediately available when the drug is given.

- **Tendon rupture:** Collagenase will damage tendons if inadvertently injected too deeply. For this reason, it is only administered by trained hand surgeons. In the
extremely unlikely event that you find that you cannot bend the finger after the injection, let Mr Warwick know.

According to the data sheet, the following are risks:

**Very common side effects, affects more than 1 user in 10**

- Reactions at the injection site like bleeding, pain, swelling, tenderness and bruising.
- Itching in the hand.
- Feeling of pain in the hand, wrist or arm.
- Swollen or enlarged glands near the elbow or under the arm.
- Swelling in the hand or arm.

**Common side effects, affects 1 to 10 in 100**

- Reactions at the injection site like pain, warmth, swelling, presence of a blister, redness of skin and/or skin rash.
- Skin wound at the site of injection.
- Painful glands near the elbows or under the arm.
- Joint swelling and pain.
- Burning sensation, partial loss of sensitivity, feeling of “pins and needles” or numbness.
- Dizziness, headache, nausea.
- Increased perspiration.

**SO THAT YOU ARE FULLY INFORMED, REMEMBER THAT THERE ARE ALTERNATIVES TO XIAPEX:**

**Needle Aponeurotomy:** less chance of pain, bruising, skin split, blister but less accurate and higher recurrence, Cheaper.

**Surgery:** lower recurrence (especially if skin graft) but much longer recovery and higher chance of a significant complication (nerve damage, stiffness, wound problems). More expensive. Scarring.

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<table>
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<th>Method</th>
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<th>COST</th>
<th>EFFICACY</th>
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**Conflict of Interest Statement**

David Warwick’s involvement has led to financial reimbursement from the company marketing the drug. This reward has included sponsorship to attend scientific meetings and professional fees for advisory work. This potential conflict of interest is declared.

David Warwick

**David Warwick’s Involvement in Xiapex and Dupuytren’s**

He was one of the first to use the drug in the UK, as Chief Investigator for a scientific study. He has continued to use the surgical drug in routine clinical practice, having performed over 360 injections by October 2015. He has also performed over 1000 operations for Dupuytren’s. Professor Warwick has led the training for use of this drug in the whole of Europe, as Chairman of the Xiapex Advisory Board. He is the lead author on several peer reviewed publications and book chapters. He is Editor in chief of the comprehensive European book on Dupuytren’s Disease. His own results have been presented at national and international meetings.

My recent Dupuytren’s papers

- **2015**

For free download of this Dupuytren’s book:
